EXHIBIT 16

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:
All Actions MDL No. 15-2666 (JNE/FLM)

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DEPOSITION OF DR. DANIEL SESSLER
VOLUME I, PAGES 1 - 152
JANUARY 11, 2017

(The following is the deposition of DR. DANIEL SESSLER, taken pursuant to Notice of Taking Deposition, via videotape, at the Cleveland Clinic, P Building, Conference Room P77-013, 2070 East 90th Street, Cleveland, Ohio, commencing at approximately 10:11 o'clock a.m., January 11, 2017.)

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PROCEEDINGS

(Witness sworn.)

DR. DANIEL SESSLER

called as a witness, being first duly sworn, was examined and testified as follows:

ADVERSE EXAMINATION

BY MS. CONLIN:

Q. Good morning, Dr. Sessler. We've not met before; correct?

A. Correct.

Q. Okay. I represent plaintiffs in an action that's been brought against 3M involving the Bair Hugger device. Do you understand that?

A. Yes.

Q. Okay. And you, in fact, were deposed a number of times in connection with this Bair Hugger device in connection with the Walton and Johnson Texas litigations; correct?

A. I was deposed a number of times. I am not sure what it was about.

Q. Okay. But you did --

You were deposed three times as it relates to your work and advice regarding the Bair Hugger device; correct?

A. Correct.

Q. Okay. And do you stand by that testimony today?
A. I do.
Q. Okay. And it was truthful and accurate at the time you gave it?
A. It was.
Q. Okay. And to the best of your knowledge it's truthful and accurate today; correct, doctor?
A. Correct.
Q. Okay. Now you are an anesthesiologist; correct?
A. I am.
Q. Okay. And can you describe your position here at the Cleveland Clinic.
A. I'm a Michael Cudahey Professor and Chair of the Department of Outcomes Research.
Q. Okay. And what is the Department of Outcomes Research?
A. It's part of the Anesthesia Institute, and we coordinate clinical research.
Q. Okay. And you do a number of clinical trials; correct?
A. We do.
Q. Okay. Now you've also -- you're a -- You're a consultant at 3M; correct?

A. I am.
Q. And that was on an exclusive basis; is that right, doctor?
A. No.
Q. Okay. Can you describe the other companies for whom you consult.
A. There are roughly 10 of them.
Q. Okay. And can you list them, please.
A. Not all of them, but --
Q. Okay.
A. -- I can mention some of them.
Q. Okay. Go ahead.
A. 3M, 37Company, CareFusion, VitaHEAT, Mercury Medical. And there are others, --
Q. Okay.
A. -- but I don't remember them offhand.
Q. And 37Company produces a product called the Mistral; is that right?
A. Correct.
Q. And do you do consulting for them today with respect to the Mistral?
A. I have not -- I serve on their advisory board, so once a year, or less often, we meet. And -- and they pay for my travel expenses, they don't actually give me cash.

Q. Okay. You're aware that 3M is the exclusive distributor for VitaHEAT now; correct?
A. I heard that, yes.
Q. Okay. What kind of consulting work do you do for them?
A. I'm on their advisory board.
Q. Okay. And do you meet regularly?
A. We've never met.
Q. Okay. Who told you that 3M was going to be the exclusive distributor of the VitaHEAT product?
A. Someone from VitaHEAT.
Q. Who was that person?
A. I don't remember.
Q. Were you involved at all in discussions with 3M as to become the -- strike that. Let me start over again.
Did you have any discussions with 3M regarding whether they should or should not become an exclusive distributor for VitaHEAT?
A. None whatsoever.
Q. Okay. Have you ever talked with 3M about VitaHEAT?
A. Never.
Q. Have you ever talked with 3M about Mistral?
A. Never.

Q. Okay. You understand how the Mistral product works as a result of your consulting work for them; correct?
A. It's a generic forced-air cover.
Q. Well, do you have any understanding, for example, of the filtration differences between the Mistral device and the Bair Hugger device?
A. No.
Q. Okay. Do you know whether the Mistral utilizes a HEPA filter?
A. No.
Q. Do you know whether the Bair Hugger utilizes a HEPA filter?
A. I believe it does.
Q. Okay. And what's that based on?
A. I have no idea.
Q. Okay. During the time -- now you -- Prior to the time that 3M bought Arizant, you were also consulting for Arizant as it relates to the Bair Hugger; correct?
A. Yes.
Q. Okay. And that work goes back 'til at least 2006; am I right?
A. Yes.
Q. Do you recall when you first started

consulting with Arizant regarding the Bair Hugger?
A. No.
Q. Okay. During the course of your consulting work for either Arizant or 3M regarding the Bair Hugger, have you ever had discussions with them regarding the filtration efficiencies of the Bair Hugger?
A. No.
Q. Do you know whether there's been any changes to the filter utilized in the Bair Hugger --
A. No.
Q. -- over the years?
Do you know whether that filtration efficiency of the Bair Hugger has been diminished through changes in filters over the years?
A. No.
Q. Okay. Now you also have a specialty in epidemiology; is that right?
A. I -- I'm not a specialist in epidemiology.
Q. Is it one of your specialties?
A. I've never taken a course in epidemiology.
Q. Oh, okay. And it's not a trick question, Dr. Sessler. The reason why I'm asking is because on your LinkedIn site it says your specialties are clinical research, anesthesia, thermal regulation and

epidemiology.
A. Many -- many of our studies include an epidemiologic aspect. Epidemiology would claim that it includes clinical research, that all clinical research is a type of epidemiology, and I was the course director for epidemiology for the medical school here for five years. But I've never taken a course in it, I don't have a degree in it, I'm -- I'm not really an expert in epidemiology.
Q. You don't have a -- a -- an expertise, then, in how bacteria can be aerosolized or moved in the environment?
A. Absolutely not.
Q. Okay. Now you've spent time with Michelle Hulse Stevens at 3M; is that right, doctor?
A. I -- I know Michelle, yes.
Q. And you've worked with her; correct?
A. Correct.
Q. And have you talked with her at all about the litigation that's going on involving the Bair Hugger?
A. No.
Q. Okay. Have you talked to her about the issues surrounding the warming/cooling devices?
A. I don't even know what you're referring to.

Q. Are you aware --
So have you been aware at all of the CDC's investigation of a device -- warming/cooling device manufactured by Sonnenschein that has been claimed to have created infection risks in cardiac patients?
A. I'm sorry, I didn't catch the name of the device.
Q. Sonnenschein.
A. Never heard of it.
Q. Okay. Are you --
Notwithstanding the name, are you aware that the CDC is conducting an investigation regarding the mycobacterium chimaera outbreak that resulted from aero -- aerosol -- aerosolized particles in the exhaust of the warming/cooling units during cardiac surgery?
A. No.
Q. Do you have --
You are an expert in normothermia though; correct, doctor?
A. Again, I don't have a degree in it, I've never studied it, but it's been an interest of mine.
Q. Okay. And a lot of the papers that you've published have -- have talked about the need for maintaining normothermia during surgeries; correct?

A. Correct.
Q. Okay. Now do you know --
With respect to Michelle Hulse Stevens, can you describe what your advisory role is to 3M today as it relates to warming devices?
A. I guess I'm theoretically on an advisory board, but the board has not met for several years at least.
Q. When is the last time you saw Dr. Hulse Stevens?
A. I don't remember.
Q. Would it have been in the last couple of years?
A. Oh, yes.
Q. Okay. And you also know Gary Hansen; correct?
A. I do.
Q. You worked with him when he was part of Arizant and you've worked with him now that he's part of 3M; correct?
A. Correct.
Q. Have you talked with Gary Hansen about this litigation?
A. No.
Q. Have you talked with Gary Hansen about 3M's

interest in acquiring an exclusive distribution license for VitaHEAT?

A. No.

Q. Would you expect Gary Hansen to be truthful and honest with you as it relates to your advisory work on warming devices for 3M?

A. Yes.

Q. And do you know an Al Van Duren?

A. I do.

Q. And how long have you known Mr. Van Duren?

A. Probably two decades.

Q. Okay. And when did you first start working or getting to know Mr. Van Duren?

A. Al Van Duren was an early employee of Augustine Medical, and I started working with the company, I think, shortly after it was founded.

Q. And in fact, you were aware as early as the '90s that a study that you had conducted involving normothermia in colorectal surgeries was being used as a basis for saying that Bair Hugger forced-air warming would be appropriate to keep patients warm in surgery; correct?

A. Which dates?

Q. Well the -- I believe that study was in 1996. Right?

A. Correct.

Q. Okay.

A. This is Andrea Kurz's New England Journal paper.

Q. Correct.

A. Yes, 1996.

Q. And -- and with your blessing, you've understood that that's been one of the papers that has been utilized to tout the use of Bair Hugger warming during surgery; correct?

MR. GORDON: Object to the form of the question.

MS. DIFRANCO: Go ahead.

A. Not with my blessing. They just use it.

Q. Well you're -- you --

A. Lots of -- lots of companies use it.

Q. Yeah. But you've been aware that they've used it in promotional literature; correct?

A. Yes.

Q. And would you expect Mr. Van Duren to be candid and honest with you as it relates to the work that -- in consulting work you've done for them on the Bair Hugger device?

A. Yes, I would.

Q. Okay. Now you have a confidentiality agreement with 3M; correct?

A. I do.

Q. Okay. And is it fair to state, doctor, that 3M has funded studies that -- on Bair Hugger that you've been a part of?

A. Yes.

Q. Okay. And they've used that work to promote Bair Hugger; correct?

A. I assume, yes.

Q. Okay. And again, that's been with your approval; correct?

A. They don't need my approval and they don't ask for my approval. And any company can use any published study in -- in any marketing material.

Q. Let me ask it a different way. You've never contacted them and said, "I don't want you using my study on Bair Hugger to promote the device;" correct?

A. I've never contacted any company in a similar situation.

Q. And my question is more specific, relates to 3M. You've never contacted 3M and complained about their use of your study on Bair Hugger in connection with promoting the device; correct?

A. I've never contacted any company.

Q. And 3M included; correct, doctor?

A. Correct.

Q. And you understand that 3M has promoted the Bair Hugger for use in all types of surgeries; correct?

A. I can't really comment on their marketing. It's not something I follow.

Q. Well you've said that the Bair Hugger is -- is safe for use in all surgeries; correct, doctor?

A. I believe that.

Q. Okay. Including orthopedic implant surgeries; correct?

A. Correct.

Q. I'm going to hand you what's been marked, Dr. Sessler, previously as Exhibit No. 17, which is an excerpt out of a CDC proceeding that took place in November of 2015, and I'd like to direct your attention to page 27 of this and give you a moment to read the last paragraph on this page and see if that refreshes your recollection on issues surrounding the warming/cooling units being used during cardiac surgeries.

Does that refresh any recollection of issues going on regarding the warming/cooling units?

A. None whatsoever.

Q. Okay.

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A. I have no idea what this is about.
Q. Okay. Have you kept up on whether the CDC is of the viewpoint that things that blow air in operating rooms shouldn't be used?
MR. GORDON: Object to the form of the question.
A. No.
Q. Okay. Would that be something that would be important to you to know in connection with your promotion of the use of the Bair Hugger device?
MR. GORDON: Same objection.
A. I'm not sure how to answer that question.
Q. Why?
A. What was the question?
Q. Question is: The fact that the CDC is suggesting that nothing that blows air should be present in an operating room, is that something that you think would be important to know --
MR. GORDON: Object to the --
Q. -- in connection with your promotion and suggestion that the Bair Hugger device is appropriate for use in surgeries?
MR. GORDON: Object to the form of the question.
A. I'd be more interested in the data on which

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their opinions were based.
Q. Okay. And you haven't done an investigation on that; right?
A. No.
Q. And in fact for years, doctor, you've been suggesting to 3M that they should do a microbial study as it relates to the Bair Hugger; right?
A. I did suggest a study, yes.
Q. On multiple occasions; correct?
A. Possibly. Probably.
Q. And they've refused to date; correct?
A. Correct.
Q. Have they told you why they've refused?
A. No.
Q. Do you know who made the decision at 3M?
A. No.
Q. Do you know who made the decision at Arizant?
A. No.
Q. Okay. Do you think the fact that the CDC is recommending that nothing that blows air in an operating theater should be present, if possible, is something that a reasonably prudent manufacturer of a forced-air warming device should take into account?
MR. GORDON: Object to the form of the

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question, also lack of foundation.
A. I don't think I'm qualified to answer a question about what manufacturers should do.
Q. Okay. If you were a science advisor for 3M and were aware of this, would you think that this would be something that you would want them to investigate in order for you to thoroughly undertake your role as a science advisor to a company?
MR. GORDON: Same objections.
A. I have not been advising them on this issue.
Q. Okay. But you are advising them on forced-air warming.
A. I am.
Q. Okay. In connection with advising them on forced-air warming, do you think the fact that the CDC is suggesting that nothing be in an operating room that blows air would be something that you would want to discuss and consult with them on?
MR. GORDON: Same objections.
A. Not necessarily.
I'd like -- I'd like to see what this is based on. This just seems to be free-form opinion as far as I can tell.
Q. Okay. But in any event, you've never been apprised of the warming/cooling units and the CDC's

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investigation by anyone at 3M; correct?
A. This is the first I've heard of it.
Q. Okay. Now I'd like to talk with you a little bit, and I -- I don't intend to waste your time here today, doctor, so I'm not going to go back through everything on your prior testimony, that's why I asked you at the beginning, you know, if you're standing by that testimony, but I would like to ask you a few questions about your study.
(Discussion off the stenographic record.)
BY MS. CONLIN:
Q. I've handed you, Dr. Sessler, what's been previously marked as (Belani) Deposition Exhibit 16, and this is a published study by you, Dr. Olmstead and Dr. Kuelpmann; is that correct?
A. Correct.
Q. And this was published in the International Anesthesia --
A. Analgesia & Anal --
Anesthesia & Analgesia.
Q. Thank you.
-- publication in 2011; correct?
A. Yes.
Q. Okay. And you're the lead author on this; is that right, doctor?

A. Yes.
Q. Okay. And if we could take a look at the bottom of the paragraph on the right-hand side of the page right before the "METHODS" where you say, "We thus tested the hypothesis that laminar flow performing -- performance remains well within rigorous and objective standards during forced-air warming." Do you see that?
A. I do.
Q. And then I take it that includes you in the "We?"
A. Yes.
Q. Okay. Then you say under "METHODS," "We evaluated the effect of forced-air warming on laminar flow performance under three test conditions," and then you list them there; is that right?
A. Yes.
Let me be clear. I did not do the testing for this.
Q. Well that's what I was going to ask you. Because as I read this article, you talk about "We then quantified tracer particle counts near the site of the putative incision...," and I'm just wondering how you can describe it as "We" if you weren't present for any of the testing.

A. Oh. That's absolutely conventional in writing a paper that the people have different responsibilities within a study. Sometimes there are hundreds of authors on a paper, literally, and they have different contributions to the study. For instance, you might have a pathologist and his contribution is to read slides and interpret them, and you would still say we as a corporate authorship did something.
Q. The purpose of this was to evaluate the effect of forced-air warming on the disruption of laminar flow; is that right?
A. Yes.
Q. Okay. And as you indicated, you weren't there when the testing was done; correct?
A. Correct.
Q. You --
3M was in control of this study; correct?
A. Well I think it was Dr. Kuelpmann.
Q. Well you understood that 3M had a commercial interest in it; correct?
A. Of course, uh-huh.
Q. Okay. And 3M created the protocols; correct, doctor?
A. I don't know who did the -- created the protocol.

Q. If you had testified previously that 3M created the protocols, would you stand behind that today?
A. Sure.
Q. Okay. And you weren't even aware that the study was proposed or conducted until after the testing had been done; correct?
A. That's correct.
Q. Okay. And you weren't involved in designing the protocols; correct?
A. Correct.
Q. And you don't have an opinion on the design of the study; correct?
A. The design seems fine.
Q. If you had testified previously that you don't have any opinion regarding the design of the study, would you stand behind that testimony?
MR. GORDON: Object to the form of the question.
A. Based on my looking now, the design seems fine.
Q. Okay. You were in fact sent simply an Excel spreadsheet with the raw data on it; right?
A. Yes.

Q. Okay. And you would agree you're not an expert in laminar flow or particulate counts; correct?
A. Correct.
Q. And you're not an expert on how bacteria travel through the air; correct?
A. Correct.
Q. And bacterial issues that might be present in hip and knee implants are outside your area of expertise; correct?
A. Correct.
Q. And you would assume that the relative risk for an orthopedic surgery by way of infection would be similar to a colorectal surgery or something else; correct?
A. Oh, not at all.
Q. Okay. So how would you describe the relative risk, as you understand it, of bacterial issues and infections in hip and knee implants?
A. It's less than a tenth of what it is during colorectal surgery.
Q. And how do you know that?
A. The incidence of infection has been published widely.
Q. My question might have been inartful. Let me ask it a different way.

You don't have an understanding of how many CFUs is necessary to create an infection in a hip and knee implant versus, as an example, another type of surgery not involving an implant; correct?

A. No. No.

Q. You don't know if it takes one colony forming unit to create an infection in an orthopedic implant; correct?

A. I'm not an expert in this field. My understanding is it takes a whole lot more than one.

Q. And I -- I take it that's been your understanding as you've advised companies on the effectiveness and safety of forced-air warming devices.

A. Host defense is the critical way that bacterial infections are prevented.

Q. Right. And do you know whether that host defense mechanism is impeded or lessened in connection with an orthopedic implant?

A. Any implant makes infections not necessarily more likely but more serious and certainly harder to treat.

Q. Okay. But it's your belief as you sit here today, doctor, that -- that you don't need -- or that you could have an infection with an orthopedic implant

with one CFU.

A. I didn't say that, and I'm not sure I agree with it.

Q. Okay. I'm saying you don't know; right?

A. I don't know.

Q. That isn't something that you've studied and -- and become an expert on; correct?

A. Correct.

Q. Do you think that's important to know when you're advising companies on the safety and effectiveness of forced-air warming in all surgeries?

A. I can only comment about things I know about in -- in all contexts. I'm not an expert in everything. I -- I comment about what I know about.

Q. Right. But you know that you've been saying that forced-air warming is safe for all surgeries --

A. Uh-huh.

Q. -- and my question is: If you don't know whether in an orthopedic implant it requires very few CFUs to cause an infection, how you can be saying that?

MR. GORDON: Object to the form of the question.

A. Infections are multifactorial. Probably the single-most-important factor is host defense, and

keeping people warm enhances host defense.

Q. Is it fair to state that you haven't studied the issue of whether forced-air warming is safe for use in orthopedic implants?

A. That depends on what you mean by "safe." We have done studies with forced air in hip and knee surgery, and the patients seemed to do just fine.

Q. What studies are those, doctor?

A. Well the first one was probably Schmid in 1996, but there have been a number of others since then.

Q. Well you haven't -- I --

You're talking about other authors or things that you've read; correct?

A. No.

Q. What do you -- what --

Well then describe the work that you've done on this.

A. The study I mentioned was a study of blood loss in patients who were warmed or not warmed who were all having hip surgery.

Q. How does that relate to the relative infection risk of Bair Hugger in an orthopedic surgery?

A. It doesn't. You asked me if it was safe. I

said we've studied it and the patients did fine.

Q. Have you done any work to ascertain whether a Bair Hugger increases the risk of infection for patients undergoing knee or hip implants?

A. No.

Q. In fact, doctor, you are agnostic, so to speak, in terms of how you keep patients warm; right?

A. Absolutely.

Q. It can be an electric blanket, it could be a resistive heating. Your view is a patient does better if they're warm; correct?

A. Correct.

Q. But you're not saying that a patient does better by way of infection risk if a Bair Hugger is used versus another type of warming device; correct?

A. No.

Q. And in fact, you don't want patients to get hurt; right?

A. Of course not.

Q. And if the --

If Bair Hugger was killing patients, you'd be the first to state it; right, doctor?

A. I would.

Q. Now what is Cleveland Clinic using in surgeries today for warming?

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A. We use forced-air warming.
Q. What type?
A. Mistral.
Q. And why was the decision made to use the Mistral?
A. It was less --
MR. GORDON: Object for lack of foundation.
MS. CONLIN: You may answer.
A. It was less expensive.
Q. Was there a review done as to whether Mistral was safer than the Bair Hugger?
A. I have no idea. I'm not involved in supply-chain decisions.
Q. Okay. You didn't have any discussions with anybody who was in the supply chain?
A. I did not.
Q. Okay. So you were just --
You know that at one point in time Cleveland Clinic was using Bair Hugger; right?
A. I --
Sure.
Q. And now they've switched to Mistral; is that right?
A. That's correct.
Q. Okay. Do you know whether it's because

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Mistral has better filtration than the Bair Hugger?
A. I was not involved in the decision-making process, but my understanding is it was purely a cost decision.
Q. Okay. And who told you it was purely a cost decision?
A. I don't remember.
Q. Now I'd like to go to the study, (Belani) Exhibit 16, and talk with you a little bit about it.
You evaluated the effect of the Bair Hugger on laminar flow performance under three conditions; correct?
A. I -- I'd have to review the study. I haven't looked at this in --
Q. Go ahead.
A. -- since the last deposition.
Q. Go ahead.
A. Yes, we used three conditions.
Q. Okay. And the -- it was --
The control was the Bair Hugger off; correct?
A. Yes.
Q. And then it was also -- second condition was the forced air of the Bair Hugger was sent to -- set to ambient air; correct?

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A. Yes.
Q. And then the third was set to high or hot air.
A. Correct.
Q. Forty-three degrees Celsius; correct?
A. Correct.
Q. And the people who did the testing basically used two blankets, the Bair Hugger 522 upper body blanket and the 635 underbody blanket; correct?
A. Looks like it.
Q. Okay. At two hospitals, right, Amersfoort and Utrecht?
A. Yes.
Q. Okay. Now did you talk with any of the people that actually did the testing?
A. Yes.
Q. Okay. Who did you talk with?
A. I talked with Ruediger and -- and Russ.
Q. Do you know --
And that's Dr. Olmstead?
A. Correct.
Q. Do you know if Dr. Olmstead was even present during the testing?
A. I don't -- I don't know.
Q. Do you know who was present during the

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testing?
A. The testing was primarily done by Ruediger.
Q. By Dr. Kuelp --
How do you say that?
A. Kuelpmann.
Q. Kuelpmann? Do you know whether --
Do you know what his involvement was in the testing?
A. He did the tests.
Q. Do you know whether Gary Hansen did the tests, doctor?
MR. GORDON: Object to the form of the question.
A. Gary was there. My understanding is that Dr. Kuelpmann did the tests.
Q. Okay. And was that based on him telling you that?
A. No.
Q. What was it based on?
A. I said it was an assumption.
Q. Now if we lake --
If we take a look at the second page of this, on the right-hand side, midway down at the bottom of the first full paragraph on page 1417, which is also Bates number 985629, it says that the standard

DIN 1946 was chosen because it is objective and more rigorous than the United States standard. Do you see that?

A. No. I'm in a different place.

Q. It's right here.

A. Okay. Now I'm with you.

Yes.

Q. Okay. Do you --

Now the DIN 1946 standard governs laminar flow rooms --

A. Yes.

Q. -- in Europe; correct?

A. I believe so.

Q. Do you know whether that D -- DIN standard forbids the use of forced-air warming in laminar flow rooms in the EU?

A. At the time we wrote this paper, I'm pretty sure it did not.

Q. And what's that based on?

A. Well I did look at the standard at one point.

Q. So at the time you submitted this paper, you thought that the -- that forced-air warming could be used under the DIN standard in the EU; correct?

A. That was certainly my impression, yes.

Q. Now you also write on the right-hand side of this second page, quote, "The forced air blower was positioned on the floor at the volunteer's left side, near where the anesthesiologist would normally sit during surgery." Do you see that?

A. Yes.

Q. Do you know if these were new machines or used machines?

A. I don't know.

Q. That wasn't something that was of interest or import to you?

A. No. Because as far as I know, age of the machine is not relevant to the question here.

Q. You don't know whether the machine --

Well you understand the air intake is at the bottom of the machine, correct, on the floor?

A. I'll take your word for that.

Q. Okay. Have you ever examined the machine?

A. I've used these machines thousands of times, but I couldn't testify to where the air intake is.

Q. Okay. Have you asked 3M or Arizant for any information regarding whether the air intake absorbs bacteria near the floor of the OR?

A. No, I didn't, because it's filtered in the machine. What comes out is sterile.

Q. And how do you know that, doctor?

A. As far as I know, all forced-air warmers contain relatively good filters.

Q. And you're making the assumption that the 3M one does as well; correct?

A. Correct.

Q. If I told you the filtration efficiency was 53 percent, would that surprise you?

MR. GORDON: Object to the form of the question.

A. Yes.

Q. Okay. I'm going to hand you, Dr. Sessler, what's been previously marked as Deposition Exhibit 66. It's actually a two-page document, so I'd ask you to start on the second page and then read up to the first.

Have you had a chance to read it?

A. Yes.

Q. Okay. Were you aware that Arizant and 3M were getting calls from the field from users of the Bair Hugger that were concerned about infectious pathogens that were being found in the machines?

MR. GORDON: Object to the form of the question, lack of foundation.

A. No.

Q. Okay. Do you see at the top there where Mr. Van Duren says, "Remove and discard the filter (in the biohazardous waste)?" Do you see that?

A. Yes.

Q. Now if the machine that you were using in surgery was contaminated with a microorganism, let's say MRSA, would you want to know whether that filter was going to filter that pathogen properly?

MR. GORDON: Object to the form of the question.

MS. DIFRANCO: Go ahead.

A. It's a two-part question.

Q. In what way?

A. Can -- can we break this apart? If -- if a machine's contaminated and --

Q. Well all right, that's -- that's a fair correction. Let me back up.

If a machine was contaminated with MRSA, would that be something as an anesthesiologist you would want to know before you decided to use that machine on a patient?

A. Sure.

Q. Okay. And if --

And would you also want to know whether the filter was able to prevent MRSA or some other pathogen

from moving downstream from the filter into the hose and into the blanket?

MR. GORDON: Object to the form of the question.

A. Yes.

Q. Okay. Have you ever seen anything where 3M or Arizant have advised publicly that if a machine is con -- found to be contaminated, that the filter should be scrapped and treated as biohazardous waste?

A. No.

Q. Okay. Have you seen any documents or had any discussions with 3M regarding advice they have given to people who have called in, users of the Bair Hugger, that you should not blow the dust out of the machine?

A. No.

Q. Would that be something that you'd want to know?

A. That -- that sounds pretty technical. I'm -- I'm not sure how to interpret that.

Q. Okay. If we look back at your study --

Well let me ask it a different way. Let me ask you another question on that. Do you know whether, as these machines are used in surgery, after surgery, whether the pathogens build up inside?

A. No.

Q. And you've just assumed that the filter is going to do its job; right?

A. Yes.

Q. Why do you think the Bair Hugger had a HEPA filter?

A. Presumably, I was told that at some point, but I don't remember how.

Q. Okay. Now if we can look under the "RESULTS" section of this study, which is on Bates page 985630, under the "RESULTS" section you say, "With the Arizant 522 upper body cover, background par -- particle Cx were reduced to approximately 5 log by the laminar flow system, and there were no statistically significant or clinically important differences among the 3 blower settings: off, ambient air, and high." Do you see that?

A. Yes.

Q. And how did you go about arriving at the conclusion that there was no clinical -- clinically important differences between the three settings?

A. If you look at Figure 2, the columns for no air, ambient air and warm air are virtually the same height, and they're all way below the two log reduction line.

Q. Well you understand the two log reduction line --

I mean the DIN standard isn't designed to evaluate Bair Hugger; right? What you were doing was saying you can use the Bair Hugger and still meet the DIN standard; right, doctor?

A. The question was whether forced-air warming; that is, warm air disturbs laminar flow and makes it substantially less effective than it would be otherwise, so the DIN standard is highly relevant. In any case, whether or not you believe that, there's no important difference here.

Q. Okay. And if we look at Figure 2, you've got -- the scale goes from 1, 10, 100 to 1000; right?

A. It's a log scale.

Q. And then 10,000; right?

A. Yes.

Q. All right.

(Exhibit 226 was marked for identification.)

BY MS. CONLIN:

Q. I've handed you, Dr. Sessler, what's been marked as Exhibit 226, which is the raw data that Gary Hansen produced regarding the study which is reflected in (Belani) Exhibit 16, your paper.

MS. DIFRANCO: Have you a chance to look at it?

THE WITNESS: Yes.

Q. Now this is the data that went into the paper that you authored with Dr. Olmstead and Dr. Kuelpmann; correct?

A. I -- I assume.

Q. Okay. And there were five runs both with the 522 blanket and five runs with the 635 blanket; right?

A. Looks like it.

Q. Okay. And if we take a look at the 635 blanket, which is on the right-hand side of Exhibit 226, --

A. Yes.

Q. -- the 625 is the underbody blanket; correct, doctor?

A. I'll take your word for it.

Q. Okay. If you want to look back at the front of your article, it indicates that it's the underbody blanket, so --

A. I'll take your word for it.

Q. All right. So in the last run there were 28 particles measured over the -- the hypothetical surgical site with the Bair Hugger off; correct?

A. Yes. That's the average, right? It --
Q. Well it says at the top "Off."
A. No, it's -- it's raw data. Okay. Thank you.
Q. Okay? And then with the Bair Hugger at ambient temperature, the particle count over the hypothetical surgical site was 57; correct?
A. Right.
Q. So that would be a two-times increase; is that right?
A. Yes.
Q. Okay. And then if you turn the Bair Hugger on to warm, the particle count over the surgical site is 349 particles; correct?
A. Yes.
Q. Okay. So that's about a thousand-percent increase between off and the Bair Hugger on warm; correct?
A. Yes. It's about a factor of 10.
Q. Okay. About 12 times as many particles; correct, doctor?
A. Right.
Q. Okay.
A. If you look at the -- the other one -- the other run, though, it has much less effect. Also, you

need to look at the average; it's not fair to pick one run.
Q. If --
Well, it's got a p-value of .06, correct, for off?
A. Yeah. But that's the average. You're looking at one run.
Q. Right. Well you only did five runs; correct?
A. Yes. But you have to look at all five of them.
Q. Okay. Would you agree with me five runs is a pretty small sample?
MR. GORDON: Object to the form of the question.
A. No.
Q. Why?
A. Because this is a mechanical sort of setup and you should get about the same result each time.
Q. Well it has --
Looking at this raw data, the use of the Bair Hugger does have an effect on the particulate count over the hypothetical surgery site; correct?
MR. GORDON: Object to the form of the question.

A. In this run it had a very small effect, in the other run it had no effect.
Q. Okay. So how is it that you can say in the title of your paper that forced-air warming does not worsen air quality in laminar flow operating rooms when at least some of the -- well all of the runs showed at least some difference between the Bair Hugger off and the Bair Hugger on?
MR. GORDON: Object to the form of the question.
A. The average performance effect with ambient versus warm was 4.8 versus 4.8 in one test, it was 3.2 versus 3.5 in another, it was 4.8 versus 4.8 in the third, and it was 4.7 versus 4.6. There -- there's no difference there.
Q. Well that -- that's the PE, the protective effect; correct?
A. Yes.
Q. Okay. And the protective effect went down on average.
A. It was unchanged. There -- there's no important change here. Those numbers are virtually identical.
Q. You don't think that a change in the protective effect from 4.0 to 3.2 makes a difference?

MR. GORDON: Object to the form of the question.
A. No. And I especially don't think a difference from 4.8 to 4.8 or from 4.8 to 4.8 in the other study makes a difference.
Q. Why didn't you --
Why did you pool the data from Amersfoort and Utrecht?
A. Oh. Why wouldn't I?
Q. Did you make that decision?
A. Probably.
Q. Okay. Do you think that a physician would want to know that, with use of the 635 underbody blanket, the particulate count went up 12-fold with use of the Bair Hugger?
MR. GORDON: Object to the form of the question.
MS. DIFRANCO: I'll object. You're asking what other physicians would want to know?
Q. Would you want to know?
A. That was one run. That's not an accurate characterization of this study result, not even slightly accurate.
Q. Well it went up --
If you look at just the 635, the underbody

blanket between off and warm, in all five runs the particulate count went up ten-fold; right?

MR. GORDON: Object to the form of the question, mischaracterizes the -- the data.

A. How do you figure?

Q. Well in the first run with the Bair Hugger off the particulate count was 23; correct? In the first run.

A. I thought we were comparing ambient to warm.

Q. Well let's just do it this way. All right?

So in the first run with the Bair Hugger off, with -- utilizing the 635 underbody blanket, the particulate count was 23; correct?

A. Yes.

Q. Okay. And with it on ambient it was 260; correct?

A. Yes.

Q. And on warm it was 118; correct?

A. I'm sorry, I lost you here.

Q. I'm right here, doctor.

A. Oh, okay.

Q. Okay?

A. Yeah.

Q. So in that run in the 635, both in the ambient and the warm, the particulate counts went up

dramatically with the Bair Hugger on; correct?

A. Yes. But it was half with warming as with ambient, and the general theory here we're testing is that warm air disturbs the laminar flow column.

Q. And ambient air doesn't?

A. That was the theory.

Q. Whose theory?

A. I believe Scott Augustine came up with this theory.

Q. All right. Well if it was --

Let's take the off and warm then. Off it was 23; correct?

A. Yes.

Q. And warm, the particulate count went up to 118; correct?

A. In that run, yes.

Q. Okay. And you don't consider that clinically significant; correct, doctor?

A. Okay. You can't look at one run. You have to look at the averages and you have to look at both tests of the 635. You put them both together, there -- there's very little effect.

Q. Well I'm -- I'm --

I'd like to do it this way. Okay? So I'm -- I'm focused on the -- the box at the upper

right-hand corner of Exhibit 226. All right? And I understand that you want to take averages, but my question is this: If a machine, Bair Hugger machine, was contaminated with MRSA and not properly filtering, would that be of clinical significance or importance to you?

MR. GORDON: Object to the form of the question.

A. Yes.

Q. Okay. Now do you know -- do you know whether you saw Exhibit 226 as part of putting together your paper?

A. Oh, for sure I did.

Q. Okay. Let me ask you something else, then we can take a quick break.

Do you think the Mistral is as effective at keeping patients warm as the Bair Hugger?

A. I have no basis for knowing.

Q. Okay. You have done studies on resistive heating and found those equally effective to the Bair Hugger; correct?

A. Yes.

Q. What did you do to prepare for your deposition today?

A. Nothing.

Q. Okay. You didn't review any documents?

A. None.

Q. Did you talk or meet with any of the lawyers representing 3M?

A. No.

MS. CONLIN: Okay. Let's take a short break. We've been going about an hour. I've got a new area. But we'll definitely be able to accede to your schedule today. Okay?

THE WITNESS: Thank you, Jan.

MS. CONLIN: Yeah.

THE REPORTER: Off the record, please.

(Recess taken.)

BY MS. CONLIN:

Q. If we can turn back for a moment to Exhibit 226, doctor, and if we take a look at the 635 testing in the right-hand box, the 635 testing at Amersfoort with the p --

Do you see the p-value box there?

A. Uh-huh.

THE REPORTER: Your answer?

THE WITNESS: Yes.

Q. You have to say it out loud.

A. I said yes.

Q. Yes. Okay.

The p-value for off versus ambient is .06; is that right?

A. Yes.

Q. And the p-value for warm versus off is .09?

A. Yes.

Q. Okay. So in other words, if the experiment were repeated, there would be an increase in particles with the 635 blanket turned on ambient 94 percent of the time.

MR. GORDON: Object to the form of the question, also lack of foundation.

A. No, that's not what a p-value means.

Q. Okay. How -- how would you describe that?

A. It means that there was a 94-percent chance that --

That six times out of a hundred, the distribution of the data would result from chance.

Q. Okay.

A. That doesn't tell you about repeatability.

Q. Why not? Isn't a p-value, the -- the whole notion of p-value to figure out whether it's by random or predictable?

MR. GORDON: Object to the form of the question.

A. Not exactly.

Q. Okay. How would you describe the differences in p-value between off and warm for a lay person?

A. That there was one chance in 10 that the observed distribution of data resulted from chance.

Q. Say that again, doctor.

A. There was one chance in 10 that the observed distribution of data resulted by chance.

Q. Okay. But wouldn't that be saying that 90 percent of the time, then, if you ran this again, you would expect to have an increase of particulate counts as reflected in that box?

A. No, --

MR. GORDON: Object to the form of the question.

A. -- that's not what it means.

Q. All right.

A. It -- it's not even close.

Q. I've handed you, Dr. Sessler, what's been previously marked as Deposition Exhibit 12, which appears to be some e-mail exchanges between you, Gary Hansen and Russell Olmstead with respect to your paper. You can take a moment if you haven't seen it in a while.

A. Yes.

Q. Okay. Have you had a chance to review it?

A. I have --

Q. Okay.

A. -- at -- the top part. I actually didn't read the bottom part.

Q. Okay. Now why don't you go ahead and read the bottom part, too, so I can ask you some questions about that.

A. Okay.

Q. Okay. The bottom e-mail is an e-mail from Gary Hansen to you and Russ Olmstead; correct?

A. It appears to be.

Q. Okay. And it's talking about sort of how you're going to do the analysis of the data; correct?

A. It doesn't specifically talk about how to do the analysis, but it's that general topic of interpretation I guess.

Q. Well one of the things that Gary Hansen writes to you and Dr. Olmstead is "Concerning statistical treatment of the PE data" --

And that's the protective effect data; correct?

A. I -- I'm sorry, I didn't realize there was a back side.

Q. Sure. Go ahead and take a moment to read

it.

A. Okay.

Q. All right. Have you had a chance to read it?

A. I have.

Q. Okay. Now on the second page of what's been previously marked as Exhibit 12, Mr. Hansen talks with you and Russ Olmstead concerning the statistical treatment of the PE data; correct?

A. Yes.

Q. And that's the protective effect data?

A. Correct.

Q. And he's talking about two possible approaches. The first is to perform a t-test comparison; correct?

A. Yes.

Q. And what is that?

A. T-test essentially compares the difference in the means --

Well, the test is a difference in the means divided by the standard deviation, approximately.

Q. Okay. And then he writes there, "Note that none of the differences are significant to within 95 percent confidence." Do you see that?

A. Yes.

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Q. And what did you understand that to be reference to?
A. Well, doing a bunch of t-tests comparing different average results.
Q. Well isn't he noting there, Mr. Hansen, that if you use the t-test on the data that was generated in connection with the Amersfoort and Utrecht testing, that none of the differences are significant to within a 95-percent confidence?
A. That's what the note says, yes.
Q. Okay. And then he writes, "It won't escape notice that the number of samples is small;" correct?
A. Yes.
Q. Meaning that there were five runs for five minutes each; correct?
A. Correct.
MR. GORDON: Object to the form.
Q. Are you aware of surgeries that take place over five minutes?
A. That's completely irrelevant.
Q. My question is: Are you aware of any surgeries that take place over five minutes?
A. Sure.
Q. Okay. What?
A. D&C.

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Q. Okay. Anything else?
A. Ear tubes.
Q. I'd say that you're right on that one. I've had -- my kids have had a few.
You would agree with me that most surgeries are not five minutes or less; correct?
A. I agree.
Q. And an orthopedic surgery might take an hour as an example; correct?
A. Correct.
Q. Now you've actually also stated that the -- whether forced-air warming is effective or necessary in the first hour of a surgery is sort of an open question; right?
A. Depends how you define efficacy.
Q. Okay. But you've in fact stated that previously; correct?
A. Depends how you define efficacy, but yes.
Q. Okay. And you don't have any information to suggest that a Bair Hugger in use for an orthopedic surgery is somehow more effective than, say, a resistive blanket; correct?
A. We've tested two resistive blankets and they had comparable efficacy.
Q. Okay. There -- there would be no medical

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reason why you'd need to use a Bair Hugger as opposed to one of these resistive blankets; correct?
A. Resistive blankets can cause burns. And they haven't been used that much. How safe they are in terms of thermal injury remains to be determined.
Q. Okay. Setting aside thermal injury and assuming you have a safe blanket, there would be no medical reason to choose a Bair Hugger over a resistive therapy; correct?
MR. GORDON: Object to the form of the question.
A. Well if you stipulate that safety is the same, the efficacy is comparable.
Q. Okay. What if the safety of the Bair Hugger was less because it increased the possibility that bacterial pathogens could enter the surgical site?
MR. GORDON: Object to the form of the question.
A. If -- if forced air causes harm, causes complications, and you stipulate, based on nothing, that some other tech -- technique doesn't, sure. But -- but there's no basis for either of those assumptions.
Q. Okay. And in fact one of the things that you're on record as saying is that the Bair Hugger has

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been used in lots of surgeries with no evidence of injury or infections; correct?
A. As far as I know, forced air has not caused thermal injury, used correctly.
Q. Well I meant --
My question was a little different.
A. I'm sorry.
Q. You're on record as stating you think forced-air warming, Bair Hugger, is safe in surgeries and doesn't increase the risk of infection; correct?
A. I believe it reduces the risk of infection.
Q. And in --
A. Based -- based on available data, that's what you have to conclude.
Q. Okay. And in fact, one of the reasons you say that is because you say it's been used in lots of surgeries and there haven't been complaints; correct?
A. No.
Q. You haven't said that?
A. That isn't the reason.
Q. What isn't the reason, doctor?
A. I -- I believe you said that I've said that --
Let -- let's go back to your question because it was a two-part question and you -- you

attributed a thought process to me.
MS. CONLIN: Could we have the question back?
(Record read by the court reporter.)
A. No.
Q. Okay. So when you say the Bair Hugger reduces the risk of infection, you're talking about maintaining normo -- normo -- normothermia in the patient; correct?
A. No.
Well, that's the presumed mechanism, but in fact two randomized trials compared forced-air warming to no warming and both showed that infection risk was reduced. That's the only clinical evidence I'm aware of.
Q. Okay. And what -- what studies are those?
A. Kurz and Melling.
Q. Can you spell the name on the second one?
A. M-e-l-l-i-n-g-s --
Q. Okay.
A. -- I think. I'm not sure about the "s".
Q. Well Melling was prewarming; correct?
A. And intraoperative warming I believe.
Q. Do you know?
A. I believe there was an intraoperative

warming group in that study.
Q. Okay.
A. But my assertion is largely based on Kurz, --
Q. Okay.
A. -- which is a better study. It's the --
The available data shows that randomizing patients to forced air reduces infection risk.
Q. But it's the -- maintaining the normothermia that is the hypothesis for why the infection risk is reduced; correct?
A. That's certainly the presumed mechanism.
Q. Okay. And as we --
As you've described, there are other methods of maintaining normothermia in a patient besides the Bair Hugger; correct?
A. Correct.
Q. Mistral is one; correct?
A. Yes.
Q. And VitaHEAT is one; correct?
A. Yes.
Q. How would you describe the VitaHEAT technology?
A. It's an underbody resistive heater with pressure relief.

Q. It's not a forced-air warming device; correct?
A. Correct.
Q. Now if we can turn back to Exhibit 12, doctor, you write back to Mr. Hansen on November 16th of 2010; correct?
A. Apparently.
Q. And this is prior to the publication of your paper with Dr. Olmstead and Kuelpmann; correct?
A. Yes.
Q. Okay. And then you write, "Hi Gary,
"On the statistics/P-value spreadsheet, the mean value for the 422 cover (warm) in Utrecht is -- is wrong -- fortunately!" And you say, "The increase with the 635 cover on ambient or warm in Amersfoort seems substantial, roughly a factor-of-five-to-ten. The only reason it isn't statistically significant is that there were only five measurements." Do you see that?
A. I do.
Q. You would agree with me this was an underpowered study; correct?
MR. GORDON: Object to the form of the question.
A. No.

Q. Well what did you mean there when you said the reason --
Well you first acknowledge it's -- the data that you and I have been looking at is substantial; correct?
A. Yes.
Q. Okay. And a factor of five to 10; correct?
A. Yes.
Q. And then you say, "The only reason it isn't statistically significant is that there were only five measurements." What did you mean by that when you wrote that to Mr. Hansen and Dr. Olmstead before this was published?
A. If you make enough measurements, very small differences will be statistically significant even if they're not clinically important. Conversely, you can have big differences that are not statistically significant and -- and/or important.
Q. Well why did you write the only reason it isn't statistically significant is that there are only five measurements?
A. It just means that if you did enough measurements, it would become significant.
Q. Statistically significant; correct?
A. Yup.

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Q. Okay. Now in the next paragraph you say, "What clinicians will want to see is basically particle counts under three test circumstances (Off, Ambient, and Warm)." Do you see that?
A. Yup.
Q. Then you write, "Any substantial increase will still concern them and basically validate Scott's point that forced-air warming increases risk. We can try to convince them that the increase isn't important or that operating rooms still meet DIN standards, but that will be a bit tricky." Do you see that?
A. Yup.
Q. You knew that physicians would want to see whether, in an individual case such as the 65 -- or 635 testing in Amersfoort, that there was a substantial increase in particulates; correct?
A. No, that's not what that means.
Q. Okay. What -- what -- what were you saying there?
A. That first it --
Note the third paragraph where I correct the statistical approach. You need to look at all the data; you can't just pick one piece of data, one line, one run, and say this characterizes the results.
Q. Okay.

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A. That's -- that's called data selection; it's a type of research fraud.
Q. Would you agree --
A. You have to look at all the data.
Q. Would you agree with me that any substantial increase would concern clin -- clinicians?
A. Average increase, not -- not results from one run and one circumstance.
Q. Would you agree with me that any substantial increase would concern clinicians?
MR. GORDON: Object to the form of the question, also lack of foundation.
A. Any substantial increase in average values over all conditions would concern people.
Q. Okay. And then you say in the third paragraph, "Possibly the best statistical approach would be an ANOVA with cover type...;" correct?
A. Yes.
Q. And that's in fact what you guys have ended up doing; correct?
A. Correct.
Q. Okay. And ANOVA is basically analysis of variance; right?
A. Yes.
Q. And then you say, "But perhaps it would be

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best to consider the hospitals together since that isn't really a factor of interest; and the cover type could be unpaired." Do you see that?
A. Uh-huh. Yes.
Q. And in fact what you were describing there is rather than show the results from the two hospitals separately, you were going to group them together for the purposes of the paper; right?
A. Yes, because it -- that's the way it should have been done. That's -- that's the correct way of handling these data.
Q. Why is it the correct way of handling these data?
A. Because the two hospitals together characterize the general case better than either hospital alone.
Q. Well you know that ORs are different; right?
A. Sure.
Q. Okay. That can be a confounding factor; right?
A. Could be.
MR. GORDON: Object to the form of the question.
Q. Could be a confounding factor.
Did you do any investigation as to whether

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the machine that was used in Amersfoort might have been a used one versus a new one?
A. No.
Q. Or that there was different protocols for how they clean the OR?
A. No. But it's not relevant to this study, which used artificial particles. This had nothing to do with bacteria.
Q. Well I think we've already established you don't know whether the Bair Hugger sucks in particulates from off the floor and spews them out into the surgical site; right?
MR. GORDON: Object to the form of the question.
A. I don't think that's relevant to this study where there are 20 million particles floating around that are deliberately introduced.
Q. So it wouldn't be of clinical interest to you.
A. You -- you're confusing two different circumstances. One is whether forced-air warmers pick up bacteria, retain bacteria or somehow eject bacteria. If they do, that's a problem. A second issue, which is what this paper is about, is whether warm air interferes with the laminar flow column. Has

nothing to do with bacteria.
Q. Okay. And you -- you --
I think we've established this. You're not an expert on laminar flow or how particulates move in the environment; right?
A. I'm not.
Q. So you -- you basic --
Did you ask anybody why it was that the Amersfoort data appeared so different in terms of the particulate counts?
MR. GORDON: Object to the form of the question.
A. I don't remember.
Q. Was it of interest to you?
A. Absolutely.
Q. What do you recall doing in connection with that data?
A. When you do multicenter studies, it's absolutely routine and normal for the results to differ in the various centers. You -- you expect that just by random motion. And it's also true that the centers are truly different; they have different operating rooms, different anesthesia, different protocols, so you expect real differences among sites in a multicenter study. But you do a multicenter

study to enhance generalizability. You take all the results you have and you put them together and you present the average because that best characterizes what you know, and that's what we did here.
Q. And in this case you did five samples, five runs five minutes each in two hospitals; correct?
A. Yes.
Q. And in fact you noted here that there were only five measurements; right?
A. Correct.
Q. So you're standing behind your proposition that this is not an under -- underpowered study; correct?
MR. GORDON: Object to the form of the question.
A. Correct.
Q. Could pooling the data from Amersfoort and Utrecht confound the data?
A. No.
Q. Why not?
A. "Confounding" has a specific meaning, has to be something that's related to exposure and outcome. I don't see how pooling induces confounding.
Q. Now I think we talked about this before, but Gary Hansen did the first draft; is that right?

A. Yes.
Q. And then Dr. Olmstead took a crack at it; is that right?
A. Yes.
Q. And then you edited it; correct?
A. "Edited" is a generous term. Virtually every word in the published manuscript was mine.
Q. I've handed you, Dr. Sessler, what's been previously marked as Deposition Exhibit 79, which is a marked-up draft of your study which eventually was published and has been previously marked as (Belani) Exhibit 16; correct?
A. Yes.
Q. Okay. And you were part of this editing process; correct?
A. Yes.
Q. If we can take a look at draft -- the draft page seven, which bears Bates number 50592, and if we can look at the middle paragraph starting with "We found..."
A. Yes.
Q. Okay. Midway down there there is a section which in this draft reads, "There were noticeable differences in the results between the two operating rooms, probably the result of small differences in

draping around the OR table, and also perhaps due to differences in the laminar flow systems." Do you see that?
A. I do.
Q. And there was a deleted box beside that, and what was deleted is "The significantly higher counts seen with the blanket model 635 reflected conditions at OR Amersfoort" or "A..." Do you see that?
A. I see it, yes.
Q. Okay. Who made the decision to delete from this transcript that there had been significantly higher counts seen with the underbody blanket at the Amersfoort hospital?
A. Well, whoever edited the document.
Q. Do you know if that was Mr. Hansen at 3M?
A. I have no idea who was editing at this point.
Q. Okay. Was that something that you had drafted originally, that you had found significantly higher counts seen with the blanket model 635 in Amersfoort?
A. I'm not sure I understand the question.
Q. My question is: Do you know whether you were the person who originally put in the draft that there had been significantly higher counts seen with

the underbody blanket at Amersfoort hospital?
A. I have no idea. Sorry.
Q. You don't recall.
A. Not even vaguely. This is from when, 2011, and this was years before that.
Q. Well if you were the one who put it in, presumably you -- you put it in originally because you thought that would be of interest to clinicians; correct?
MR. GORDON: Object to the form of the question, lack of foundation.
A. We don't know that I put it in.
Q. Well it's consistent with the e-mail exchange we just went through; correct?
MR. GORDON: Object to the form of the question.
A. It requires supposition.
Q. Well would you agree that this statement is consistent with your -- the deleted statement is consistent with your statement as reflected in the e-mails we just went through, Exhibit 12?
MS. DIFRANCO: Here.
(Document handed to the witness.)
A. The statement seems consistent with the data. Who put it in, who took it out, I have no idea.

Q. Okay. You'd agree with me that the DIN standard that is mentioned in your paper is not designed to detect increased particles from a forced-air warming device; correct?
A. The DIN standard was designed to evaluate the efficacy of laminar flow.
Q. Have you ever -- have you ever advised 3M on sort of any reporting requirements that it may have for infections that people are claiming that they got as a result of use of a Bair Hugger in their surgery?
MR. GORDON: Object to the form of the question.
A. Not at all. That's nothing I have any expertise in.
Q. Okay. I've handed you what's been previously marked as Deposition Exhibit 67, and you can take a moment and look at it.
MR. GORDON: Has Dr. Sessler signed the protective order?
MS. DIFRANCO: I think he did last time.
MS. CONLIN: Yeah. I -- I mean he's got an exclusive consulting relation. I mean I asked -- that's why I asked him at the beginning if he's under confidentiality with 3M.
MR. GORDON: All right. But I -- I --

One thing has nothing to do with the other. You think -- you think he did sign this --
MS. DIFRANCO: I think he did --
MR. GORDON: -- protective order?
MS. DIFRANCO: -- in the other case.
MR. ASSAAD: I believe so.
MS. DIFRANCO: Yeah.
MR. GORDON: Okay.
A. Okay.
Q. Okay. The bottom is a communication between Al Van Duren and Linda Johnson; correct?
A. It appears so.
Q. Okay. And it -- it says, "To be brief:
"Received a number of complaints regarding infections.
"2) Within the MDR reporting requirements you are exempt from reporting (Bold Emphasis Mine) based on CFR803.20..." Do you see that?
A. I do.
Q. Okay. And then it bolds that "you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury..." Do you see that?

A. I do.
Q. And then there's -- in the top e-mail there's a reply from Mr. Van Duren to Ms. Johnson with a number of attachments, and I don't know what was written here because it's been redacted, but do you see that in the attachment, the first one is your -- your article?
A. Yes.
Q. Okay. Do you think that your article supports a view that microbial infections can't happen with the Bair Hugger?
MR. GORDON: Object to the form of the question.
A. Would you mind repeating that question?
Q. Sure. Do you believe that your study supports the proposition that microbial infections cannot occur through use of the Bair Hugger?
MR. GORDON: Object to the form of the question.
A. That seems like a little bit of a convoluted wording, so let me answer by saying that I don't believe that this study supports risk from forced-air warming in terms of infection, and it has to be put in context with other available studies that show that forced-air warming reduces infection in actual

patients, not in laboratory simulations.

Q. And my question was a little bit different. Do you think your paper supports the proposition that a patient cannot become infected through use of a Bair Hugger?

MR. GORDON: Object to the form of the question.

A. Again this is convoluted wording, but I believe my study shows that forced-air warming does not substantively increase risk.

Q. Based on your five -- five samples of five minutes apiece; correct?

MR. GORDON: Object to the form of the question.

A. That's all you need for a laboratory-based simulation.

Q. Okay. But you haven't --

I mean if it puts it to bed, Dr. Sessler, then why have you been urging Arizant and now 3M for some time to do a study on this issue?

MR. GORDON: Object to the form.

A. The trouble with this study and all the similar studies is that they're laboratory simulations; they don't involve patients, they don't involve bacteria. These -- these are not -- this is

not a study of bacteria, it's a study of particulates that are put into the air intentionally to see what happens to them. The obvious next step, if you're concerned one way or the other, whether you believe it's true or whether you don't believe it's true, the obvious next step is to do a study that at least goes into an operating room and involves real patients. That's what I told them.

Q. And why have they refused to do that?

MR. GORDON: Object to the form of the question, lack of foundation.

A. I haven't a clue.

I propose studies all the time. Companies agree to support a small fraction of the ones I propose, and they make their own -- decisions for their own reasons.

Q. Okay. No one's ever expressed to you why they refused to do one?

A. No.

Q. Okay. Now you're doing some current studies for 3M; correct?

A. I am.

Q. Okay. Well actually, before we get to that, have you talked with 3M at all about whether they have an obligation to --

I mean have they ever told you that they're getting reports, receiving a number of complaints regarding infection?

A. No.

Q. Okay. And you've never had any discussions with them on that?

A. No.

Q. What do you do as a science advisor for 3M in their -- on forced-air warming?

A. Well as I said, we haven't met for a long time, but the advisory board when it meets discusses various issues. The last meeting was all about prewarming; that's essentially all we talked about.

Q. Okay. But in all these science advisory meetings you've never had a discussion regarding whether use of Bair Hugger can disrupt the currents in the OR?

A. I don't remember that being a topic of a meeting.

Q. Okay. And in all these science advisory meetings you haven't had discussions about whether the Bair Hugger device itself can harbor microbes?

A. Not that I remember, no.

Q. Now I think you testified earlier that you understood that 3M had a commercial interest in this

study that we've been talking about; correct?

A. You mean the Anesthesia & Analgesia --

Q. Correct.

A. -- number (Belani) 16?

Q. Correct.

A. Yes, of course they have an interest.

(Discussion off the stenographic record.)

BY MS. CONLIN:

Q. I've handed you, Dr. Sessler, what's been previously marked as Deposition Exhibit No. 11. I'm actually going to ask you about the middle e-mail on page two bearing 24810, and it appears to be --

Do you know who Teri Woodsock-Sides is?

A. Yes.

Q. Woodwick-Sides.

Have you met her before?

A. Yes.

Q. In what context?

A. She worked for Arizant and then I believe for 3M.

Q. Okay. And it says, "Dear Thomas and Ron,

"Great job in recapping the presentations. It is very powerful that Professor Kulpman is speaking (independently) on the topic of forced-air warming and laminar flow. One reason that we are holding the data

was to allow time for results to be written up and submitted for publication. We have a researcher in the US interested in co-authoring this research."

That person turned out to be you; correct?

A. It looks like it.

MR. GORDON: Object to the form of the question, lack of foundation.

Q. Okay. And do you know whether it was after April 23rd of 2010 that you were first contacted regarding the work that Professor Kuelpmann had done that ultimately became the paper that was co-authored by the two of you?

A. I have no idea.

Q. Okay. Then you see it says, "That said, these results are also part of a legal strategy, which we have been carefully outlining. It is important for our longer-term goals that we do not release it too prematurely." Do you see that?

A. Yes.

Q. Were you aware that the study that 3M contacted you on was part of a legal strategy?

MR. GORDON: Object to the form of the question.

A. No.

Q. Nobody ever told you that?

MR. GORDON: Same objection.

A. No.

Q. Would that have been something that you would have wanted to know when they contacted you and said, "We've conducted this study and would like you to be an author on it?"

MR. GORDON: Same objection.

A. No. That the study was of interest to them and was part of their legal strategy I -- I guess was pretty obvious.

Q. So that doesn't surprise you.

A. No, it doesn't surprise me. But I don't think I was specifically told. I -- I have not read this previously.

Q. Did you ever go back to them and say, you know, "I think we should have additional sampling points and perhaps we should go back and do some additional work at Amersfoort?"

A. No.

Q. No discussion on that at all?

A. No.

Q. Do you oftentimes find yourself as a consultant to a company that is part of their legal strategy?

MR. GORDON: Object to the form of the

question, lack of foundation.

A. Not often, no.

Q. Okay. I mean they -- 3M --

3M put together the protocols for this study; correct?

MR. GORDON: Object to the form of the question.

A. Yes.

Q. And 3M personnel conducted the study, Gary Hansen along with -- I think you said Professor Kuelpmann might have been there; right?

A. Well I believe Dr. Kuelpmann conducted the study.

Q. Okay. We established this before. You don't know.

A. That's correct.

Q. Okay.

A. I said I believe.

Q. Okay. And they sent you the raw data.

A. Correct.

Q. And they sent you a draft manuscript that was written by Gary Hansen.

A. Correct.

Q. And this was part, as you see now, of a legal strategy; correct?

MR. GORDON: Object to the form of the question, lack of foundation.

A. Yes.

Q. And you worked on it -- I --

I take it you accepted the raw data as accurate?

A. I did after discussion with Dr. Kuelpmann.

Q. Okay. Did you talk with Gary Hansen about it at all?

A. Yes.

Q. What did you talk with Gary Hansen about, if you recall?

A. I don't recall.

Q. Now you're doing some consulting work, doing some new studies for 3M; is that right?

A. Yes, but --

We are doing studies. It's not consulting though.

Q. Okay. Fair enough. You make a dis -- distinction between when you're -- when 3M is funding a research project versus when you're doing consulting work for them; correct?

A. Absolutely.

Q. Okay. And I --

Is it true that when you're doing consulting

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work for them, such as like on the 3M advisory board, that's billed separately than if they give you -- if they fund a study and give you money for that; correct?

A. Correct.

Q. Okay. When they fund a study, does it impact your salary at all or -- or your total compensation?

A. Absolutely not.

Q. Okay. Your --

How much funding you get from various companies doesn't impact the salary that you're paid.

A. Not at all.

Q. Okay. And can you describe for me what current studies you're performing that 3M is funding right now?

I'm sorry, --

A. Yes.

Q. -- let me withdraw that and ask a more specific question.

What funding is 3M giving you on issues of studies relating to either the Bair Hugger, forced-air warming, or normothermia?

A. Okay. There are three studies.

Q. Okay.

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A. Two are registry analyses and one is a randomized trial.

Q. Okay. Why don't we start with the three registry analyses -- or the --

A. Two registry.

Q. -- two registry analyses.

A. Okay. One evaluates the relationship between core body temperature during surgery and post-operative myocardial injury.

Q. Okay. And what's the name of that study?

A. I don't believe it has a --

I mean it has some -- some name, but I don't know what it is.

Q. Project Protect?

A. No.

Q. Okay.

A. Protect is the randomized trial.

Q. Okay. All right. Okay. And where is that being conducted?

A. Here.

By "that" you mean the registry study?

Q. Yes.

A. Yeah.

Q. The one that --

A. Both registry studies are here.

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Q. Okay. And what -- tell me what the setup on those registry stud -- what --

What's the second registry study?

A. I'm not sure. I'm sorry, I don't remember at the moment. It -- it's some --

It's the relationship between the intraoperative core temperature and something, --

Q. Okay.

A. -- but it's not infection.

Q. And describe the difference between a randomized --

A. I don't think -- I don't think it's infection.

Q. Okay. Do you know if it is?

A. I don't remember the study offhand, but I -- I don't think so. I --

Q. What is the Spot On project?

A. That's been completed for several years.

Q. Would it --

What was it?

A. It was an evaluation of a Spot On temperature monitoring system.

Q. Okay. Why don't you describe the second registry study for me again. I missed it when you described it.

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A. Well I described the first registry study, which was core temperature and myocardial injury.

Q. Right.

A. The second one I didn't describe because I can't remember what it is at the moment.

Q. Do you know if it relates to Bair Hugger infections?

A. I -- I don't think so, but I would have to look it up to be sure.

Q. Okay. I'm going to request that you do that.

And then what is the randomized trial that's going on?

A. That's --

Q. Project Protect?

A. -- Protect. Protect hasn't started yet, but it will be a randomized trial of very mild hypothermia versus aggressive warming with the primary outcome of myocardial injury.

Q. Okay. The working hypothesis is even small decreases in body temperature can put patients at risk for myocardial issues?

A. Yes. Or perhaps, turned around, that aggressive warming reduces risk.

Q. What warming modalities are you using in

that randomized trial?
A. Forced air.
Q. Just the Bair Hugger?
A. Yes.
Q. And where is that taking place?
A. Some patients will be enrolled here, but the bulk of the study will be done in centers in China.
Q. Okay. And what's the -- what's the -- the protocol? What -- what's the test method?
A. Take -- take patients at risk for myocardial injury, randomize them to very mild hypothermia versus aggressive warming, and see whether they develop myocardial injury.
Q. So you're actually going make patients mildly hypothermic?
A. In China most patients are not actively warmed, so even the mildly hypothermic group probably gets more warming than they would get otherwise.
Q. So in China, it's basically taking regular patients and then using the Bair Hugger on another set and seeing whether there's a difference in myocardial injury?
A. I'm not sure I understand the question.
Q. Well you said you're taking patients who are mildly hypothermic. You're not inducing mild

hypothermia in the China study, or are you?
A. Patients are enrolled based on risk, and consent of course, and then in the mild hypothermia group they're allowed to cool to 35.5 degrees and then actively warmed to prevent further hypothermia. In the aggressive warming group, patients will be prewarmed and then they'll be aggressively warmed intraoperatively with two different forced-air covers, surgery permitting, with a goal of having a core temperature of 37 degrees at the end of surgery.
Q. How many patients are you enrolling?
A. We plan 5,000.
Q. How many will be here versus China?
A. Here will be probably fewer than 200.
Q. When do you expect to have that complete?
A. Three or four years.
Q. When they were asking you to do this randomized trial, did you go back to them and talk to them about the fact that you still were wondering about the infection risk with the Bair Hugger?
A. They didn't ask me to do the study. I -- I proposed it, many times, actually, over the course of several years, and finally they agreed.
Q. Okay. How much is the trial? What's the funding on the trial, or the budget?

A. It's some modest amount: a couple hundred dollars per patient.
Q. No. I meant what's the overall cost of the trial?
A. I think it's about 1.6 million, most of which is a pass-through to the sites doing the study.
Q. Are you doing, other than those three projects, any other projects on forced-air warming for 3M?
A. I don't believe so.
MS. CONLIN: I'm going to go into a new area, so this might be a good time to take a short break. I don't know if --
We can go off the record.
THE REPORTER: Off the record, please.
(Luncheon recess taken.)

AFTERNOON SESSION
BY MS. CONLIN:
Q. This morning, Dr. Sessler, I had asked you about whether you had any information regarding the filtration efficiency of the Bair Hugger. Do you recall that testimony?
A. Yes.
Q. Okay. Or questioning I should say.
I've handed you what's been previously marked as Exhibit 6, which is an e-mail between various individuals at 3M.
Have you met a Karl Zgoda before?
A. Not that I recall.
Q. Okay. But Gary Hansen you have; correct?
A. Correct.
Q. And Ryan Barrows?
A. Not that I remember.
Q. Okay. And as you see, it says, "As we discussed this morning, please find the media efficiencies (prior to pleating and filter assembly)," and do you see down there on M20 it's got a 58-percent efficiency at three microns?
A. Yes.
Q. Okay. That isn't --
MR. GORDON: It's actually .3 microns.

MS. CONLIN: Point three, thank you.
Q. Point three microns. Do you see that, doctor?
A. I do.
Q. And that's not something that you've ever discussed or been aware of with respect to the M20 filter used in the Bair Hugger.
A. Correct.
Q. Now the report that -- or the paper that you published with Dr. Olmstead and -- Drs. Olmstead and Kuelpmann underwent a peer-review process; is that right?
A. Yes.
Q. And you'll recall that a number of the reviewers were concerned that there was a conflict of interest by the authors of that study: yourself, Olmstead and Kuelpmann; correct?
MR. GORDON: Object to the form of the question.
A. I don't recall.
Q. I'm going to hand you what's been previously marked as Deposition Exhibit 80, and if you want to take a moment and review that.
A. Okay.
Q. Okay. Does this refresh your recollection,

Dr. Sessler, that during the peer-review process of your article there were a number of concerns about whether the study was being done to promote the Bair Hugger product?
A. I have no recollection of the peer-review process.
Q. Okay. But in any event, that's what the section editor of the Anesthesia & Analgesia publication said; correct?
A. As -- as I read this, the editor is saying because there are conflicts of interest, that the manuscript should be squeaky clean, which I agree with completely. And we complied.
Q. And they said, "You do not provide a good scientific reason to do the study. It might appear that the study was conducted to promote Arizant's products." Correct?
A. Did say that.
Q. Okay. And when the editor wrote you that, did anybody tell the editor that the study was part of 3M's legal strategy --
MR. GORDON: Object to the form of the question.
Q. -- in connection with the Bair Hugger?
MR. GORDON: Object to the form of the

question.
A. I didn't.
Q. Do you -- do you know if anyone did?
A. I don't know if anyone did.
Q. Okay. One of the things that he says is, "You don't provide a good scientific reason to do the study." What did you understand the reason that you were pulled into that study?
At the time, you didn't know it was part of a legal strategy; right?
A. No. But there were publications saying that forced -- (clearing throat) excuse me -- that forced-air warming disturbed laminar flow, and this study was designed to address that concern.
Q. Okay. So it was for the purposes of commercial promotion of the product; correct?
A. No.
MR. GORDON: Object to the form of the question.
A. No. Not at all. To -- to answer the question does forced-air warming interfere with laminar flow.
Q. Did 3M ever tell you that they viewed your study as having limitations?
A. Come again?

Q. Did --
Well I'll ask it more directly. Did Michelle Hulse Stevens ever tell you that she viewed your study as having limitations?
A. She didn't. But all studies have limitations.
Q. Do you know -- have you ever --
Do you know Dr. William Reed, Bill Reed?
A. I don't believe so.
Q. Okay. How about Dr. McGovern?
A. I don't believe so.
Q. Okay. Do you know who Mr. Gauthier or Mr. Albrecht are?
A. Mr. Albrecht was an employee of Augustine Biomedical, and that -- that's the sum total of what I know about him.
Q. Have you met him before?
A. I don't believe so.
Q. Okay. Those were two individuals whom you and Dr. Olmstead tried to prevent as being peer review -- peer reviewers on your article; correct?
A. I don't remember. I'll take your word for it.
Q. Well if you testified to that previously, that would have been a little closer in time; correct?

A. Little closer, yes.
Q. Okay. Do you -- do you have any recollection of why you would have suggested that those two not be peer reviewers on your article?
A. Yes. It seems -- I guess I -- I thought they had a -- a bias in a different direction and that they might not be fair reviewers.
Q. Well you had a bias in one direction; didn't you, sir?
A. I'm not sure I would agree with that. I wanted to find the answer.
Q. Well you -- you weren't even involved in the study. You were approached by 3M after it was -- the testing had been done; right?
A. Yes.
MR. GORDON: Object to the form of the question.
A. But I --
Q. And --
A. I had an interest in publicizing the results because I thought they were clear and that the message was important --
Q. Did you --
A. -- and that they addressed the controversy.
Q. Did you look at the protocols and whether

there was a conclusion written at the protocols before the testing took place?
A. I don't remember the details.
Q. Okay.
A. I -- I simply don't.
Q. Okay. Do you think that would be important to know, whether it was conducted in a way to have a certain outcome base?
A. How the study is conducted is certainly important, and I certainly did review how the study was done.
Q. Now we talked -- when he's pulling that out -- we talked a little bit this morning about your understanding of epidemiology, and I just want to make sure that I have this correct.
You've never done any analysis of the number of bacteria or a bacterium that can cause an infection of an implanted foreign material; correct?
A. Correct.
Q. And whether that happens through an airborne route.
A. Correct.
Q. Okay. And you would agree with me that soft-tissue infections are -- require a much larger inoculation, correct, because of the host defense that

you've described?
MR. GORDON: Object to the form of the question.
A. Larger -- larger than what?
Q. Than a joint implant.
A. I don't know that.
Q. Okay. It's not something that you've ever studied or looked at.
A. It's really not my area.
Q. Okay.
(Discussion off the stenographic record.)
(Exhibit 227 was marked for identification.)
BY MS. CONLIN:
Q. I've handed you, Dr. Sessler, what's been marked as Exhibit 227, which is -- appears to be --
The bottom is an e-mail from Al Van Duren to various members at 3M, including Gary Hansen.
Do you know who Gary Maharaj is?
A. Yes.
Q. You've met him before?
A. Yes.
Q. Okay. And it's reflecting on a telephone call that Al Van Duren had with you on September 21st, 2010. Do you see that?

A. Well I haven't read this yet.
Q. Okay. Go ahead. Sorry, sir.
A. Okay.
Q. Okay. And this is Al Van Duren reflecting a conversation that he had had with you the previous day; correct?
MR. GORDON: Object to the form of the question, also lack of foundation.
MS. CONLIN: You may answer.
Q. See it says, "I talked to Dan Sessler yesterday?"
A. It appears to say that, yes.
Q. Okay. And in the next paragraph it says, "Dan suggested that we conduct a microbiological study by placing culture dishes in the sterile field for a fixed duration and analyzing the CFUs." Do you see that?
A. Yes.
Q. And it goes on to state that you thought you were pretty confident that the cost of the study would be modest and there would be no significant differences in outcomes; correct?
A. Correct.
Q. And that was way back in 2010; right?
A. Correct.

Q. And this was the -- what we talked about this morning. 3M hasn't undertaken that suggestion even today; correct?

A. Not that I know of.

Q. And you actually got upset with 3M about their refusal to do a bacterial contamination study; correct?

A. Where does it say that?

Q. Do you recall being upset with 3M, that they wouldn't undertake a bacterial study --

A. No.

Q. -- as you proposed?

A. No.

Q. I've handed you, Dr. Sessler, that's -- what's been previously marked as Deposition Exhibit 14, which the cover page appears to be an e-mail from you to Gary Hansen. I'll give you a moment to review it.

A. Yes.

Q. Do you recall this exchange?

A. No.

Q. Do you see, if we can take a look at page two of it, it starts with an e-mail from Steven Shafer at Stanford. Do you see that?

A. Okay. I -- I've only read the first page so far.

Q. Oh, okay. Why don't you go ahead and take a look at the whole document.

A. Okay.

Q. Have you had a chance to review it?

A. I have.

Q. Does this refresh your recollection that Dr. Shafer, who was then editor in chief of Anesthesia & --

A. Analgesia.

Q. -- Analgesia wrote you in August of 2012 regarding the publication of your study?

A. Yes.

Q. Okay. And he raises a number of criticisms; correct?

A. He does.

Q. Okay. And he said, "We have received a credible report suggesting that your recent paper in Anesthesia & Analgesia misrepresents the safety of forced air warming." Do you see that?

And it says, "The --

A. Yes.

Q. -- "complaint we have received is quite detailed," and then he lists a number of issues with your paper; correct?

A. Correct.

Q. Okay. And he goes on to state, "I don't find the concerns about your intentions credible. Thus, your intentions are not in question. The question before us is entirely scientific: is your study description accurate (e.g., the statement that it complies with an accepted standard), and are your conclusions fully supported by your findings?" Do you see that?

A. I do.

Q. Okay. And one of the things that they -- criticism they had is that you didn't measure the effects of rising waste heat from forced-air warming devices; correct?

In number six.

A. Yes.

Q. Okay. And in fact, I think you've testified previously that it's your understanding that the Bair Hugger generates about 400 watts of heat.

A. Correct.

Q. About 80 of which are absorbed by the patient; correct?

A. That's about right.

MR. GORDON: Object to the form of the question.

Q. And 320 of those watts then go into the operating room; correct?

A. Correct.

Q. And then it goes on to say, "Your study omitted two of the standard test procedures." Do you know what that was about?

A. No.

Q. And it says under number one, "The 'standard' test procedures were not designed to test forced air warming devices." Do you see that?

A. I do.

Q. Okay. And do you know what that was about?

A. Not offhand.

Q. Okay. And then you write, in response to this e-mail from the editor of the journal in which your study was published, you write to Gary Hansen, Al Van Duren and Russ Olmstead as well as Dr. Kuelpmann; correct?

A. Correct.

Q. And you say, "Hi Folks,

"We have a problem, in the form of an official complaint, obviously from Scott Augustine, about the laminar flow paper."

Why did you assume it was obviously from Scott Augustine?

A. I don't remember why I assumed it.
Q. Okay. Have you ever seen any publications by doctors at Stanford that raise concerns about the lack of filtration efficiency in Bair Huggers?
A. Not that I remember.
Q. Are you aware of an outbreak of Acinetobacter baumannii --
Did I pronounce that correct?
A. Acinetobacter.
Q. Thank you. Yeah, Acinetobacter.
-- that occurred in a hospital in Kentucky?
A. No.
Q. Are you aware that after they changed the Bair Hugger filters, the outbreak stopped?
A. No. But that's meaningless.
Q. "Meaningless." What do you mean?
A. That's a typical regression-to-mean, before-and-after type issue. That's scientifically meaningless, to do before-and-after studies that -- that have almost no scientific value --
Q. Well --
A. -- because --
Q. -- if -- if you're out there promoting the safety of the Bair Hugger, aren't these things that you should actually know about, doctor?

MR. GORDON: Object to the form of that question, argumentative.
A. I can't know everything.
Q. But in any event, it's meaningless to you; right?
A. Before-and-after data are absolutely meaningless.
Q. And the fact that the outbreak stopped after changing of the Bair Hugger filter doesn't matter to you as somebody who's out there promoting the safety of Bair Hugger; is that right?
MR. GORDON: Object to the form of the question.
A. That is absolutely meaningless data. Before-and-after studies are confounded by the fact that many things change simultaneously. You have a Hawthorne effect, you have regression to mean. It's just of no value.
Q. Okay. And my question was a little bit different. If somebody is out there promoting the safety of Bair Hugger, it's not important data to you; right?
MR. GORDON: Object to the form of the question.
A. What's not important data?

Q. The fact that they found Bair Huggers contaminated with this particular bacteria, had an outbreak in the hospital, and the outbreak stopped after they changed the filters and cleaned the machine.
MR. GORDON: Object to the form of the question, it misstates -- mischaracterizes the facts.
A. With what you've told me, I can't tell whether this is important or not.
Q. Okay. But in any event, it's not something that you knew about; right?
A. I'm sorry, I didn't hear that.
Q. It's not anything that you knew about before today; correct?
A. I did not.
Q. Okay. So you write to, in connection with this letter by Dr. -- or e-mail from Dr. Shafer of Stanford University, you write to Gary Hansen, Al Van Duren, Russ Olmstead and Dr. Kuelpmann; right?
A. Yes.
Q. Okay. And you say in the second sentence, "Steve wants to discuss the issue with me on Sunday and I need to have a full and convincing response ready. Unfortunately, this topic is well outside my area of expertise so I'm going to need your help." Do

you see that?
A. I do.
Q. Okay. Is it your position, at least as reflected in this e-mail, that the questions raised about your study were outside your area of expertise?
A. Some of them were for sure.
Q. Why don't we go through on --
On the seven points raised, why don't you tell me which ones are outside your area of expertise.
A. Number one I don't think is relevant. Two and three are outside my area.
Q. Well okay. One, is one outside your area of expertise?
A. I'm not sure how to answer that. I don't think it's relevant.
Q. Okay.
A. I --
Q. But in any event, do you claim to have any expertise in DIN standards?
A. No.
Q. Okay. Number two, "Your study omitted two of the standard test procedures" for DIN. Is that something within -- that you can talk about?
A. No.
Q. Okay. How about number three, "Your study

omitted the second part of the standard test procedure used in the study?"

A. No.

Q. Not within your area of expertise.

How about four, "You modified the standard procedures so that the results would support this device?"

A. Part -- partially in my area.

Q. Okay. In what way?

A. Well I -- I don't think we did modify the -- the standard procedures, and the modifications we made were not designed to support a particular conclusion.

Q. Okay. Well you weren't involved in the upfront part of this; --

A. That's fair. Fair -- fair --

Q. -- is that right?

A. -- enough. Fair enough. But --

Q. So I mean --

A. -- the -- the protocol, as -- as I understand it, was designed to get the right answer, not to prove a point.

Q. Okay. But you don't know whether that protocol actually was designed to get a particular answer.

A. Doesn't so matter -- much matter why it was

designed or what the theory was. Either it addresses the question -- either the test procedures are appropriate and answer the question or they were not appropriate.

Q. Okay. Number six, "You did not measure the effects of rising heat waste from forced air warming devices," that's outside your area of expertise; right?

A. We did measure the effects of rising heat. That was the whole point of the study.

Q. Where in your study does it talk about rising heat?

A. It's the comparison between the ambient temperature and the heated condition. It's exactly testing that.

Q. For five minutes.

A. The measurement was for five minutes.

Q. Thank you.

A. It's -- it's a laboratory test. You don't need to measure it for ever and ever. It doesn't change.

Q. And then it said, seven, "You detected" -- "You studied the device in an artificial setting where the rising waste heat phenomenon was least likely to be detectable over the surgical site - restricting the

heat to the head end of the patient." Do you see that?

A. I see that.

Q. Is that within your area of expertise?

A. Yes.

Q. Okay. And what would be your response to number seven?

A. About 90 percent of all forced-air warming is done with upper-body covers, and so that is the relevant condition.

Q. Then you say, in this next part of your e-mail forwarding the inquiry by Dr. Shafer at Stanford, you say, "I suppose I should point out the obvious. For a year I've been saying that the only way to put this issue to bed is to do a clinical bacterial sampling study. We should have had those results by now -- which would fully address this issue. As is, we're again playing catch up. It was a foolish decision not to do that study long ago." Do you see that?

A. I do.

Q. And that's consistent with what you've been testifying here today; correct?

A. I still think the study would be useful.

Q. Okay. And then Gary Hansen writes back on

August 31st and says, "There is much to say, and I've already worked through most of it. Let me pull it together." Do you see that?

A. Yes.

Q. Okay. And then you write Gary back on that same day and say, "Gary,

"I'm pretty unhappy. I took this project on as a favor and it has ended up costing a huge amount of time -- and now more to come. Further, this may damage my reputation; just the fact that a complaint was filed already has to some extent." Do you see that?

A. I do.

Q. Okay. And so you took this project on not for scientific reasons but as a favor to 3M as reflected in this e-mail; correct?

A. No. I took it on to try to answer the question because I thought the literature that was being published misstated the circumstances.

Q. Well what did you mean when you said, "I took this project on as a favor and it has ended up costing a huge amount of time" and that it may damage your reputation? What were you referencing there?

A. Well the -- the fact that a complaint has been filed certainly is potentially damaging. Just

the fact that a complaint is filed is damaging even if it turns out to be okay.

Q. What do you mean when you say, "I took this project on as a favor...?"

A. Well I wasn't paid for it, if that --

This was not a contract. I didn't get paid for this.

Q. Okay. And then you go on to say, you know, "I've been talking about doing a bacterial sampling study;" right?

A. Yes.

Q. Then you go on to say, "I'm under -- I'm underwhelming with the way Arizant/3M is being managed. It has taken forever to get the analysis for DTT."

What's that?

A. Deep temperature thermometer.

Q. Okay. And it says, "As a result, you're going into your big launch without a validation paper even submitted, much less in the press." What's that a reference to?

A. That they're launching a product without a validation paper in press.

Q. What's a validation paper?

A. It's a study showing that the product works.

Q. Okay. Do you know whether the Bair Hugger was launched without a validation paper?

A. Yes.

Q. Yes, it was launched without a validation paper, or yes, you know?

A. Yes, it was launched without a validation paper.

Q. Okay. Do you know it --

It got approval at the FDA as a 510(k); correct?

A. I believe so.

Q. Okay. Do you know what the predicate device was that was used for that 510(k)?

A. No.

Q. Do you know whether it was a cast drying device that was manufactured in 1937 through 1943?

A. I -- I know nothing about the approval process.

Q. Did you talk with Mr. Hansen, either by e-mail or over the phone or in person, regarding your e-mail to him of August 31st, 2012?

A. Probably, but I don't remember.

Q. I've handed you, Dr. Sessler, what's been previously marked as Deposition Exhibit 218, which appears to be minutes of a Global Patient Warming

Advisory Board meeting of October 18th, 2012, showing you present with others. You can take a moment, if you'd like, to review it.

A. This goes on for a long time. Do you want me to read the whole thing?

Q. Well no. I mean what I'm going to do is ask you about certain things and see if you remember them, and if you want to take a moment and review on either side, you're welcome to do so.

A. Well let's do it that way.

Q. Okay. Do you remember being at a Global Patient Warming Advisory Board meeting?

This is the advisory board meetings that you described earlier today; correct?

A. It is.

Q. Okay. Do you get minutes of these meetings?

A. No, I don't.

Q. Okay. And if we look down under the "Summary," there's the proposed troponin study --

A. Tro -- troponin.

Q. -- troponin study by you, and -- and you described that earlier today. Is that that randomized trial?

A. That's correct.

Q. Okay. I forgot to ask you: What was the

Spot On trial that is concluded? That related to the Spot On device; is that right?

A. Yes.

Q. Okay.

A. Or wait, wait. I'm sorry. What was the question?

Q. Well we talked about the Spot On trial earlier today, and I was --

A. Yes.

Q. -- just --

I couldn't remember what the technology was in it.

A. It's a zero heat flux.

Q. Meaning what?

A. Meaning it's a surface thermometer that's heated --

Basically, it's a heat flux transducer and a heater, and you servo control the heater to no heat flux, at which point there's -- the device becomes a perfect insulator by definition, and you get a little tunnel of warmth that goes down about a centimeter. You put the thermometer some place like the forehead where one centimeter down is core temperature, then you can read core temperature quite accurately from the skin surface.

Q. Thank you.
And then if we look under -- and this is all part of the summary -- if we look at the last section of the summary of this advisory board meeting, under "Other" it says, "Board approved of proposed 3M/CCL particulate study to counter 'Blowing Air Is Risky' claim from competitors; particularly interested in looking at patient prep phase since clinicians often do not use forced-air warming here." Do you see that?
A. I do.
Q. So as part of your work on 3M's advisory board, you were advising them on how to counter some of the statements that Scott Augustine was making; correct?
A. Yes.
Q. And had you been involved in that?
A. Not at all.
Q. Other than advising --
A. I -- I'm --
Q. -- them and --
A. Well I --
Q. -- telling them to move forward on it?
A. I was certainly not involved in this study that's being talked about here. I don't even know what it is --

Q. Okay.
A. -- or if it ever happened.
Q. Well you were at the meeting though. Do you remember anything about this?
A. No.
Q. Okay. Do you think it's appropriate in your role as a scientific advisor to be advising and improving -- or approving competitive campaigns?
MR. GORDON: Object to the form of the question.
A. My goal is always to get the right answer and to get the truth out.
Q. Now you know Dr. Augustine well; correct?
A. I know him -- I've --
I've known Dr. Augustine for more than two decades, --
Q. Okay.
A. -- not well. I haven't talked to him in years.
Q. Okay. There was a point in time in which you wanted an interest in his Hot Dog company; correct?
A. No.
Q. That never happened?
A. No. He approached me and asked me to become -- be an advisor for him, and I declined.
Q. Okay. And did part of your --
Did you discuss with him whether you would, if you accepted that position, take an ownership interest in the company?
A. Yes.
Q. And what was that discussion?
A. It was just an absolutely routine negotiation about, if he wants me to do something, what do I expect in return.
Q. Okay. And as part of that, it was an actual piece of the company; correct?
A. Yes.
Q. And Dr. Augustine said no; right?
A. We mutually disagreed. I -- I don't -- I don't think he objected to my having ownership in the company. We couldn't agree on an amount.
Q. Okay.
A. It was just an absolutely standard negotiation.
Q. Okay.
A. Nothing unusual about it.
Q. And that was prior to the time you went on the 3M science advisory board?
A. I don't know.

Q. So if we can take a look at page six of this, Dr. Sessler, it bears the last three Bates numbers 445. Do you, Dr. --
By the way, Dr. Sessler, do you have shares in any patient-warming company?
A. Yes. I have stock options, I think, for VitaHEAT --
Q. Okay.
A. -- that date back before their current arrangement with 3M. But any fees or compensation I get, including stock options, related to warming, I donate to charity. I've done this for -- for many years, and I've made it absolutely clear to everyone that -- that all this work is -- is essentially pro bono.
Q. You weren't involved in advising 3M in connection with its arrangement with VitaHEAT?
A. Absolutely not.
Q. Okay. Did you know that 3M was considering taking an exclusive license to VitaHEAT?
A. I had no inkling.
Q. So if we take a look at page six, this is under the heading --
Well it's your proposed study in China; right?

A. I don't know. I'm sorry, I haven't read this yet.

Q. If you look at the page before, in five there's a heading, and would this have been a presentation that you made at this meeting, or are these a summary of the points that you made at the meeting regarding your proposed study in China?

A. It -- I believe it was a presentation.

Q. Okay. And then at the --

If we look at the two bullet points at the top of page six, there's a notation, "Kurz 1996 SSI paper limitations," and it says, "only 200 patients, mostly superficial infections with few clinical consequences (we should focus on deep tissue/organ SSIs), the factor of 3 risk increase is not plausible (30 percent or so is more likely)." Do you see that?

A. Yes.

Q. Was that information that you presented during this advisory meeting at 3M?

A. Apparently.

Q. Okay. Then you went on to say, "Melling paper seriously flawed: only 420 low risk patients, infection was not defined, core temperature not recorded (!)" See that?

A. Yes.

Q. Do you agree that the Melling paper is seriously flawed, as you stated to 3M?

A. Yes.

Q. Okay. And do you agree with me that you told 3M that the Kurz 1996 SSI paper has limitations and you identified them to 3M?

A. All papers have limitations.

Q. Okay. Now if we go down --

Well, and you in fact mentioned these limitations on the Kurz study to 3M at this meeting as reflected in these notes; correct?

A. Yes.

Q. Okay. Then we go down and it's got sort of a -- almost like a Q&A. It says "Question: why should 3M fund a study to show risks associated with hypothermia when there is already broad acceptance of current evidence?"

And then there's a "DS." Is that referring to you?

A. I assume.

Q. Okay. It says, "the threat to 3M is that the old studies will begin to be discredited."

Is that a reference to Melling and Kurz?

A. Probably.

Q. Okay. "Once this begins it will pick up

speed and leave you exposed. Large outcomes studies are needed to take the place of the old studies."

Is that something that you recall mentioning to 3M at this meeting?

A. No.

Q. Okay. Do you deny that you said it?

A. Oh, no. It looks like I did, I just don't recall it.

Q. Okay. Then if we take a look at page seven, midway down it's "Hooper/laminar flow in hip/knee replacements." Do you recall what that's about?

A. Only vaguely.

Q. Okay. What is the Hooper/laminar flow in hip/knee replacements?

A. I know --

I don't remember the study, so I know nothing except what I'm reading right here, which is not enough for me to discuss it.

Q. Okay. And do you see that Al Van Duren said, "Shows laminar flow is not effective. But potentially could be interpreted to mean that forced-air warming disturbs laminar flow, causing laminar flow not to work." Do you recall him saying that?

A. No.

Q. And if we take a look on the last page, page eight, it says, "Discussion of new aerobiology study to counter the 'BAIR' misinformation." And it says, "GH" -- I assume that's Gary Hansen -- "presented study proposal. Board supported the idea."

Then it goes on to say "DS" -- which is you -- "Host defense protects against SSI much more than sterile ORs and external conditions. This study would take the wind out of the 'BAIR' argument. That is the only reason to do it."

Do you see that there?

A. Yes.

Q. Does that sound like a statement you would have made?

A. I -- I don't really know what the new aerobiology study is, so I don't think I can comment here.

Q. Okay. We did talk today a little bit about your view that the host defense protects against surgical-site infections; right?

A. Host defense is absolutely critical.

Q. Okay. But you don't know whether --

Well let me ask it this way: What is the host defense if a bacterium lands on an implant, like a knee?

MR. GORDON: Object to the form of the question.

A. Host defense still applies.

Q. Okay. Do you know whether the host defense is significantly impeded in connection with an implant?

MR. GORDON: Object to the form of the question.

A. I -- I don't know. I believe that -- I simply don't know.

Q. Okay.

(Exhibit 228 was marked for identification.)

BY MS. CONLIN:

Q. I've handed you, Dr. Sessler, what's been marked as Exhibit 228, which appears to be an e-mail between you and Scott Augustine with a copy to Bob Buehler.

Do you know a Bob Buehler?

A. Yes.

Q. Who is that?

MS. CONLIN: Is your phone going off? Do you need step out?

MS. DIFRANCO: It's mine.

MS. CONLIN: Okay. I want to -- I know

you're a doctor, so I wanted to make sure. All right.

Q. Who is Bob Buehler, or do you know who Bob Buehler is?

A. I do know Bob Buehler. He worked for Scott. I don't know his title or role.

Q. Okay. And this is dated 2000, and if we could take a look at the third paragraph down, you write, "I do not at all support the statement that 'forced air is the standard of care.' For one thing, it's not even a true statement! More than half of all patients in the United States (to say nothing of the world) do not receive force-air warming."

Now this is written in 2000, but did you believe that to be accurate when you wrote it?

A. I probably wrote it because I believed it to be accurate.

Q. Okay. And then midway down that --

Well actually, midway down it says, "After all, many patients can be kept warm with passive insulation alone. Others can be kept normothermic with less effective technologies."

Was that a true statement when you wrote it?

A. Yes.

Q. Okay. And then in the next paragraph you write, "The efficacy of electric warming blankets is

nearly the same as forced-air warming..." Was that a true statement?

A. I'm sorry, I'm not seeing the sentence at the moment.

Q. Oh, I'm sorry, doctor, right down there.

A. Oh, okay. Sorry. I was in a different paragraph here.

Q. Sorry.

A. Yes.

Q. Okay. And that's true today in your mind; correct?

A. Yes.

(Exhibit 229 was marked for identification.)

BY MS. CONLIN:

Q. I've handed you what's been marked as Exhibit 229. The cover page appears to be an e-mail from you to Al Van Duren dated April -- I'm sorry, May 30th, 2014, and attached is a study co-authored by you and others entitled "A Randomized Comparison of Intraoperative PerfecTemp and Forced-Air Warming During Open Abdominal Surgery."

Was this a study that you were involved in?

A. Yes.

Q. Okay. And what was your involvement in this

study?

A. I designed the protocol, supervised data acquisition, I supervised statistical analysis, and heavily edited -- probably wrote -- most of the manuscript.

Q. Okay. And PerfecTemp is an underbody resistive-warming system that combines servo-controlled underbody warming with viscoelastic foam pressure relief?

A. Apparently.

Q. Is this -- is this the -- the VitaHEAT?

A. I don't think so.

Q. Okay. How -- how does it differ, if at all, than the VitaHEAT product?

A. I -- I can't tell you.

Q. Okay. If we can take a look at the conclusion, which is on Bates page 694, "In summary..." Do you see that on the left-hand side right before "DISCLOSURES?"

A. Yes.

Q. Okay. You and the other authors conclude, "In summary, mean intraoperative TWA" --

That's time-weighted average; am I right, doctor?

A. You are.

Q. Okay. "In summary, mean intraoperative TWA core temperatures were no different, and significantly noninferior, with underbody resistive heating than upper-body forced-air warming. Underbody resistive heating may be an alternative to forced-air warming."

That's what you concluded in this study that was published in 2011; am I right?

A. Yes.

Q. And have you seen any counter evidence to -- that would undermine the conclusions that you reached in this study?

A. No.

(Exhibit 230 was marked for identification.)

BY MS. CONLIN:

Q. I've handed you, Dr. Sessler, what's been marked as Exhibit 230, which is an e-mail exchange between Niya Johnson and Michelle Hulse Stevens with a copy to Al Van Duren. Do you see that?

A. Yes.

Q. Dated November 18th, 2015, "Subject: BMW refocus: pre-warming." Do you see that?

A. Yes.

Q. And it says, "Michelle,

"I'd like to extend you an invitation to

join the BMW team call" -- or "team on a call with two KOLs and experts on pre-warming Dr. Brauer and Dr. Sessler." Do you see that?

A. Yes.

Q. What -- what is the BMW?

MR. GORDON: Objection, lack of foundation.

A. I haven't a clue.

Q. Okay. Are you working with 3M on a prewarming project?

A. No.

Q. It says "on pre-warming," do you see that, "call with two KOLs and experts on pre-warming Dr. Brauer and Dr. Sessler?"

A. I see that.

Q. Okay. But you're not aware of any work you're doing with 3M on prewarming right now?

A. We -- we are not doing work with 3M on prewarming now.

Q. Okay. Do you know if BMW refers to Bair Mobile Warming?

MR. GORDON: Objection, lack of foundation.

A. No, I don't. I have no idea what it means.

Q. Okay.

THE REPORTER: We have to change disks. Off the record, please.

(Recess taken.)

BY MS. CONLIN:

Q. I've handed you, Dr. Sessler, what's been previously marked as Deposition Exhibit 222. It starts, actually, with an e-mail from you on the third page, so you might want to start on the third page and -- and read up.

A. Oh, okay.

Okay.

Q. Okay. If we can take a look at the third page bearing Bates 541796 of Exhibit 222 first, you write to a number of people at 3M; am I right?

A. Yes.

Q. About a --

Sounds to me like there was a key-opinion-leader meeting in Washington. Was that in connection with your work for 3M or was that just on the SCIP-10 protocol in general?

A. I don't know.

Q. Okay. It says, "One of the points Andrea" --

Who is Andrea?

A. Probably Andrea Kurz.

Q. Okay.

-- "Andrea Kurz and I tried to make at the

KOL meeting in Washington is that the evidence for hypothermia-related complications mostly does not meet current research guidelines for reliability and that previous studies were done with much larger temperature differences than are currently allowed."

What do you mean by that?

A. The major trials showing that hypothermia causes complications mostly compared temperatures of about 36.5 to about 34.5; no patients now are allowed to get to 34.5.

Q. And then in the third paragraph you say, "The writing is on the wall. Without new evidence of harm from current levels of hypothermia, SCIP-10 is unlikely to survive into the next version of pay-for-performance measures."

What's that a reference to?

A. SCIP-10 is Surgical Care Improvement Project, 10 was one of many measures defining quality criteria, and warming and maintaining normothermia was one of them.

Q. And --

A. That -- that -- that's what number 10 was.

Q. And you were involved in that, right, that proposal?

A. I -- I was -- I was somewhat involved in

that, in the original version.
Q. And how would you describe your involvement?
A. I was one of many, many people. I represented the ASA, I believe, --
Q. Okay.
A. -- American Society of Anesthesiologists, at their request.
Q. And the pay for performance is a reference to the fact that because the SCIP-10 protocol is in place ensures and the government will reimburse for warming modalities in order to keep the patient normothermic; correct?
A. Not quite.
Q. Okay. How would you describe it?
A. SCIP-10 -- well, called pay for performance -- was initially only pay for reporting, so you -- if you reported what you did and the outcomes, you would get -- you would continue to be paid the normal amount. So this was independent of the outcome; all you had to do was report. Then eventually it turned into -- was called pay for performance. Actually, it was a two-percent, I think, decrease in payment if you didn't follow the measure.
Q. Okay. Thank you. It said -- and so what is your --

What was your concern about SCIP-10 unlikely to survive into the next version? What did you mean by that?
A. I -- I've been concerned for a long time that the old studies that demonstrated benefits of normothermia don't meet current standards, and -- and that's true. It's the best evidence we have. We can't ignore available evidence that shows, for example, that forced-air warming prevents infections, but the quality of the evidence is not what we would use today. The -- the quality of the studies or -- or -- is not what we would hope for today. If we were doing those studies now, we would do them differently. I --
This is not a -- really a criticism of the studies. They're mostly my studies. They were done to the standards of their time, but the times have changed.
Q. Okay. Are you involved at all in sort of the next-generation SCIP-10 protocols?
A. No. I was -- I was involved in the initial measure, and there have been several since then and I have not been involved in any of them.
Q. Okay. Then on the first page of this document, Exhibit 222, Michelle Hulse Stevens weighs

in; is that right?
A. Apparently.
Q. To a group at 3M. It says, "All,
"I think it is true that the RCT data are old and will not hold under scrutiny soon. Having said that the CDC SSS guideline draft statements on warming will continue to rec active warming but cite the need for more research on whether there are differences in modality." Do you see that?
A. I do.
Q. Okay. And RCT is a reference to randomized clinical trial?
A. Randomized controlled trial, actually.
Q. Does SCIP-10 still exist?
A. And that's a good question.
Q. It's not a trick question. I don't know the answer, which is why I'm asking you.
A. I believe SCIP-10 was require -- was retired because there was no longer a performance gap.
Q. Okay.
A. But I -- I'm not completely sure on what the current standard is. Well the SCIP -- actually, the SCIP measures broadly have been retired, so there's a whole different quality process now.
(Exhibit 231 was marked for

identification.)
BY MS. CONLIN:
Q. I've handed you, Dr. Sessler, what's been marked as Exhibit 231, which appears to be some e-mail exchanges between you and various individuals at 3M. You can go ahead and take a look.
A. Okay.
Q. So the --
This chain of e-mails starts with an e-mail from a Mark Morken. Do you know who Mr. Morken is?
A. I do.
Q. Okay. Who is he?
A. A 3M employee.
Q. Okay. Have you worked with him in the past?
A. Yes.
Q. Okay. On what kinds of projects?
A. He's one of the key contacts for Protect.
Q. Okay. And it starts out -- this was written on March 4th of 2016 -- "Hello Dan,
"Our group met yesterday to discuss the proposed retrospective review of SSI in Colorectal surgery protocol and we have the following questions or clarifications:"
Number three he writes, "The infection rate in the 1996 study went from 19 percent to 6.6 percent

and in the background for this protocol the infection rate is 13 percent - why is there such a difference from what was achieved in 1996 and the current -- current status?" Do you see that?

A. Yes.

Q. And then you wrote him back, right, --

A. I did.

Q. -- with respect to that?

And you -- you numbered your e-mail to respond to the questions he had in the e-mail to you; correct?

A. Looks like it.

Q. Okay. And in response to number three you say, "Presumably, the infection rates differ because the institutions and definitions differ. Importantly, about half the Clinic cases are inflammatory bowel disease, a group with a high infection rate, where most patients in the 1996 trial had colon cancer. The treatment reported in 1996 is implausibly high (that is, the infection rate probably wasn't actually as low as in our 100 warmed patients). Knowing what we do now about fragile clinical trials, we would never have published such a small study."

Do you see that?

A. I do.

Q. Is that a reference to the -- what's known as the 1996 Kurz study?

A. Yes, it is.

Q. Okay. And what did you mean by knowing what you know now, you wouldn't have published such a small study?

A. In 1996, 200 patients was considered a large trial. Now it would be considered a tiny study.

Q. Okay. And can you clarify for me this sentence about "The treatment reported in 1996 is implausibly high...?" Do you have evidence on that infection rate? I was just curious.

A. I'm sorry. Well --

You asked two questions there I think.

Q. Yeah. Well first you say, "The treatment reported in 1996 is implausibly high..." What are you referencing there?

A. I am not referencing anything. I'm making a statement of -- a judgment statement.

Q. Okay. So then you go on to say "...(that is, the infection rate probably wasn't actually as low as in our 100 warmed patients)," and I was just curious how you arrived at that.

A. Well what -- what I'm saying is that infections, like almost all outcomes, are

multifactorial, and therefore any one treatment tends to have a relatively small effect. Short of something like antibiotics or vaccines, we're usually dealing with 30-percent effects, not factor-of-three effects.

So the factor of three is what we got; it -- it is an accurate statement of the true results. The question is: If we repeated that study 50 times, would you get the same thing each time? Well no, of course not, we would get something different. Probably that something different would be a lot less than a factor of three.

Q. Thank you.

I've handed you, Dr. Sessler, what's been previously marked as Deposition Exhibit 39, which appears to be an exchange between you and a Martin Grady at Ameritech. Do you know who that is?

A. Yes.

Q. Who is Martin Grady?

A. Martin Grady is anesthesia staff at the Cleveland Clinic. That's just his private e-mail address.

Q. Okay. And you start out on the last page and --

A. Oh, sorry.

Q. -- say you hope you're enjoying your

vacation. You met with a company this morning that is developing a new temperature monitor. What's that a refer -- a reference to?

A. Spot On.

Q. Okay. And then you ask him a number of questions; correct?

A. Apparently.

Q. Number one is: "Do you routinely use BIS monitoring?" What is that?

A. BIS is bispectral index. It's a measure of hypnotic depth.

Q. And then number two, "Is intraoperative forced-air used and, if so, what kind of cover?" See that?

A. Yes.

Q. Okay. And then Martin Grady or Dr. Grady wrote you back, then, on April 16th, correct, --

A. Apparently.

Q. -- of 2009, and he wrote, "No forced air warming device is currently used. I think it would be a tough sell with the surgeons (surgical field concerns)." Do you see that?

A. Yes.

Q. And then you wrote him back and copied Al Van Duren, Gary Hansen and Gary Maharaj, then at

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Arizant; correct?
A. Apparently.
Q. And Al Van Duren forwards that on to Mark Scott and John Rock on that -- few days later; correct?
A. Apparently.
Q. And says, "Note Dr. Grady's reason that Bair Hugger is not used at Hillcrest (Cleveland Clinic)."
So in fact you were aware that one of the reasons that physicians at Cleveland Clinic wasn't using the Bair Hugger was because of surgical field concerns, correct, --
MR. GORDON: Object to the form of the question --
Q. -- as reflected in this document?
MR. GORDON: Object to the form of the question, lack -- also lacks foundation.
A. Actually, first, this is cardiac only. There's no indication for using forced-air warming during cardiac surgery because the bypass pump transfers a hundred times as much heat as forced air.
I didn't want them to use forced air because forced air might warm the air around the forehead and interfere with the Spot On validations we were doing.
The surgical-field concerns does not refer

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to infection; this is just simply who gets what surface area, and the surgeons doing cardiac surgery want to go right up to the neck because they split the sternum starting about here (indicating).
Q. Well he doesn't say that. He says, "I think it would be a tough sell with the surgeons" because of surgical field concerns; correct?
MR. GORDON: Object to the form of the question.
Q. Did you have a conversation with him following this e-mail about what he meant when he said, "No forced air warming is currently used. I think it would be a tough sell with surgeons (surgical field concerns)?"
A. No, I didn't. I -- I didn't want forced air to be used. Martin's opinion about forced-air warming is just irrelevant to me; he's not an expert in the subject. That the surgeons want to have access to a certain amount of surface area is perfectly reasonable, it's a surgical decision. Ultimately, anesthesia is there to help surgeons get on with their job. This -- this has nothing to do with infection or danger or anything else.
Q. Well you don't know that because you just said that you never had any conversation with him

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about this following his e-mail to you on April 16th; correct?
MR. GORDON: Object to the form of the question.
A. You can read anything you want into it, but that's not what this is about.
Q. I guess my question is a little different. You didn't talk with him about this statement at any point in time; correct?
A. No. Why would I? He says they don't use forced air and I didn't want them to use forced air.
Q. Okay. Now have you done, as part of your Outcomes --
What's the name of, I'm sorry, your --
A. Outcomes Research Consortium.
Q. Outcomes -- Outcomes Research Consortium.
Have you made presentations regarding PerfecTemp?
A. Well I imagine a study was presented at some point.
Q. Okay. Do you know whether in a PowerPoint you mentioned that one of the advantages to the PerfecTemp is that it doesn't blow air around?
A. I certainly never presented that.
Q. Okay. If your department did, would you

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take issue with it?
A. Yes.
Q. Okay.
A. But -- but it wouldn't surprise me that it happened. I don't control everything that happens in -- in my department or the consortium.
Q. Okay. But you are chair.
A. I'm a chair, but I don't control everything that happens. I'm not that kind of chair.
Q. If somebody in your group wrote that one of the advantages of the PerfecTemp -- PerfecTemp is because it doesn't blow air around, there's no chance of potential increase of contamination, would you take issue with that?
A. I would indeed.
Q. Well you'd agree with me that the PerfecTemp doesn't blow air around; right?
A. It does not.
Q. Who -- who in the department would give a presentation on the protocol for the PerfecTemp study?
A. Could be anybody, but most likely it was one of the students involved in the study.
Q. Do you have anybody that you can think of off the top of your head? Do you know which students were involved in the --

A. In PerfecTemp?
Q. Yeah.
A. Absolutely not.
Q. Okay. Well you published on it, though; right? You published on -- a study on it. Did you work with anyone in your department on that study?
A. Well certainly the co-authors of the study were involved.
Q. Okay. But --
A. There may have been other people also.
Q. But did you have somebody that -- within your group that was assisting you with that?
A. I'm not sure I understand the question. Our studies are collaborative efforts and lots of people contribute in different ways to a study, so yes, everybody assisted with it.
Q. My question might have been poor.
So there were more than one person within your group that worked on that PerfecTemp study?
A. Well it was at least all the co-authors.
Q. Okay. And those are --
So were those colleagues, the co-authors?
A. I -- I believe so. But we can pull up the --
Q. Yeah. Would you pull it up? I'm sorry to

ask that.
A. I'll tell you exactly who they are.
Q. Thank you.
A. Okay. So if I can do this without making too much of a mess here --
Okay. The co-authors were Cameron Egan, Ethan Bernstein, Desigen Reddy, Madi Ali, James Paul, Dongsheng Yang, and me.
Q. Okay. And so those are all within your department.
A. No.
Q. Okay. Which ones are in your department?
A. Well it's -- it's coded there. You can simply look at the superscripts and then look down on the bottom left and it tells you exactly --
Q. So Cameron -- Cameron --
A. Cam -- Cameron and Ethan and Dongsheng are from my department, and the other three are from the Department of Anesthesia at Hamilton General Hospital.
Q. Now you also did, back in 2007, you did -- did an underbody blanket study for Arizant; is that right?
A. I don't know what you're referring to. I'm sorry.
Q. Sure.

(Exhibit 232 was marked for identification.)
BY MS. CONLIN:
Q. I've handed you what's been marked, Dr. Sessler, a two-page document bearing Bates page 585482 through 83, which is a series of e-mails, it looks like, between various individuals at Arizant.
A. Okay.
Q. Have you had a chance to review it?
A. I have.
Q. Does this refresh your recollection that you in 2006 were working with Arizant on an underbody -- underbody blanket study?
A. Yes.
Q. Okay. And that the conclusion was that there was no significant treatment effect associated with the use of underbody blankets?
A. Correct.
Q. Okay. And did they talk with you about not publishing the results as initially reported to them?
A. Not that I remember.
Q. I've handed you, Dr. Sessler, what's been marked as Deposition Exhibit 85, which is an e-mail from you to Al Van Duren and others at Arizant dated January 24th, 2007. Bottom e-mail reads, "Good

morning, Dan,
"Thanks for your cooperation. Just be clear, I understand that you will not submit this paper for publication until we have had time to study it further." Do you see that?
A. I do.
Q. Then you write them back and you say, "Understood! We regard this as a collaborative effort to put the best face on a disappointing clinical result. Rather than a 'response,' you can make suggestions and necessary changes right in the text of the manuscript." Do you see that?
A. Yeah.
Q. And that in fact was an attempt, in connection with the underbody study, to put the best face on a disappointing clinical result; is that right?
A. We were trying to understand what the result means. The -- the difficulty with that result is that it was inconsistent with probably dozens of previous studies. There -- there's no chance whatsoever that forced air suddenly stopped working in a general sense, we know forced air warms, so there was something special about that study that led to failure then, and what I'm trying to do is understand what

that special thing is so that we know so we can interpret it. Clear -- clearly, the results of the study are that under those circumstances you shouldn't use forced air, it doesn't help, but it's -- that doesn't mean it doesn't work in other circumstances. It clearly does.

Q. Right. And you reported to the individuals at Arizant that you viewed it as a collaborative effort to put the best face on a disappointing clinical result; correct?

A. Yup.

(Exhibit 233 was marked for identification.)

BY MS. CONLIN:

Q. And in fact, you edited that paper in order to put the best face on a disappointing clinical result; correct, Dr. Sessler?

A. I don't know. I don't remember what I did.

Q. Okay. I've handed you what has been marked as Deposition Exhibit 233, a one-page document bearing Bates 518536, which is an e-mail from Gary Hansen to Al Van Duren and others at Arizant dated May 8th, 2007. Subject line is "Sessler Updated Paper." Do you see that?

A. Yup.

Q. And then Gary writes to Al, "Teri is OK with the latest version. I haven't heard back from anyone else, but basically Sessler did what we asked of him. It's now a much more favorable paper." Do you see that?

A. I do.

Q. This suggests to me that you would -- you were working with 3M, at least in connection with this underbody blanket, to put the best face on a disappointing outcome, and you took direction from 3M as to how to do that. Is that a fair reading of these e-mails?

MR. GORDON: Object to the form of the question.

A. No. Took suggestions.

Q. Well --

A. Virtually every contract we have with a company to do a study includes that they get to review the manuscript and make suggestions. They can't prevent publication; we -- we publish everything. And they don't control what's in the -- in the paper, but they are welcome to make suggestions. Many of these people are content experts in their own right. And I take suggestions seriously; I don't necessarily accept them.

Q. Well in this case they asked you not to publish it and you agreed; correct?

A. No, that's not what they asked.

Q. Well the original -- the original version of it --

A. No. No, they didn't.

Q. -- they asked you not to publish.

A. No, they didn't. Read it.

Q. "Just be clear, I understand that you will not submit this paper for publication until we've had time to study it further."

A. "...until we've had time to study it further."

Q. Okay.

A. And that's written into the contract. I don't even have a choice about that.

Q. Okay. But then they --

You agreed to that, and then they came back and --

A. I have to agree to it, it's a con -- contractual obligation.

Q. And then they came back to you and basically they repart -- report that Sessler did what we asked of him and it's now a much more favorable paper; right?

A. That's what it says.

Q. Okay. And then it says, "Unless anyone else has an opinion, I would tell him to go ahead." Does that mean and publish it?

MS. DIFRANCO: You're asking him what Gary meant -- what Gary meant when he said that?

MS. CONLIN: Yeah, it's a -- actually, that's a fair objection.

Q. Do you know that after -- whether after, following this series of e-mails, that you did go ahead and publish the underbody study?

A. It was published.

Q. Okay. Do you have a contract with 3M regarding your work?

A. There's a contract for each study.

Q. Okay. I don't know if we've seen those or not, but do they outline what you can publish and when you can publish in connection with a study?

A. The clinic will never sign a contract forbidding publication, but almost all of them include the right to review and have a reasonable amount of time to make suggestions. That -- that's just normal.

Q. Okay. And it would make sense that you would have, at the end of the day, the ultimate right whether to choose to publish something or not.

A. I absolutely have the ultimate right. And -- and we publishing everything whether it's favorable or not. It was never on the table to not publish this, the only question was how to interpret it most accurately.

Q. Or most favorably; correct?

A. Most -- most accurately.

Q. Well it was to put the best face on a disappointing clinical result; correct?

A. Make sense of it.

Q. Okay. And in connection with that 2011 Sessler/Olmstead/Kuelpmann study, did you have a contract on that?

A. No, we didn't, because it was not -- They didn't pay me for that.

Q. It was because you did a favor, as we saw in the e-mails; correct?

A. Yes.

MS. CONLIN: Okay. I don't think I have any further questions.

MR. GORDON: Take a break. I'm not sure if I do have any questions, but I'll review a couple things.

THE REPORTER: Off the record, please.

(Discussion off the record.)

MS. CONLIN: I didn't bring copies of the depositions for everyone because I'm not going into them, I just want to mark them as exhibits. I have two copies. If you can mark that.

MR. GOSS: These were the prior depositions?

MS. CONLIN: Yeah. I just want to mark them as exhibits. You can mark that. Mark this.

(Discussion off the stenographic record.)

(Exhibits 234 through 236 were marked for identification.)

BY MS. CONLIN:

Q. I've handed you, Dr. Sessler, copies of the deposition transcripts of your prior testimony in the Texas litigation that I mentioned earlier today, and my only question for you is: You gave what you believe to be truthful and accurate answers at the time you were deposed as reflected in Exhibits 234, 235 and 236?

A. I have not read these.

Q. Yeah. But I mean as you sit there today, I mean you would stand --

A. I believe what I said previously was accurate, best of my abilities at the time, but I have not reviewed the transcripts. I -- I cannot attest to their accuracy.

Q. Okay. But as you sit here today, you don't know of anything that you said in those transcripts that are not accurate today.

A. That's correct.

MS. CONLIN: Thank you. I have no further questions.

THE REPORTER: Off the record, please.

(Recess taken.)

(Mr. Gordon indicated off the record that he had no questions, and Ms. DiFranco waived signature.)

(Deposition concluded.)

CERTIFICATE

I, Richard G. Stirewalt, hereby certify that I am qualified as a verbatim shorthand reporter, that I took in stenographic shorthand the deposition of DR. DANIEL SESSLER at the time and place aforesaid, and that the foregoing transcript is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Deerwood, Minnesota, this 15th day of January, 2017.

RICHARD G. STIREWALT
Registered Professional Reporter
Notary Public